

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON TALCUM
POWER PRODUCTS MARKETING, SALES
PRACTICES, AND PRODUCTS LIABILITY
LITIGATION

No. 3:16-md-02738-MAS-RLS

MDL No. 16-2738 (MAS) (RLS)

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT
LLC'S BRIEF IN SUPPORT OF THEIR
MOTION TO EXCLUDE PLAINTIFFS' EXPERTS'
ASBESTOS-RELATED OPINIONS**

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INTRODUCTION

This motion seeks to exclude testimony related to Plaintiffs' allegations that Defendants' cosmetic talc products are contaminated with trace amounts of asbestos. Specifically, Defendants seek to exclude: (I) Plaintiffs' testing expert's opinion purporting to find chrysotile asbestos in Defendants' talc; (II) Plaintiffs' testing experts' opinions purporting to find amphibole asbestos in Defendants' talc using transmission electron microscopy; (III) Plaintiffs' causation experts' opinions that asbestos causes ovarian cancer; (IV) Plaintiffs' geologists' opinion that the talc ore Defendants used as a source was contaminated with asbestos; and (V) Plaintiffs' causation experts' backup theory that "fibrous talc" acts like asbestos and causes ovarian cancer.

The focus of this motion is the work of Plaintiffs' expert Dr. William Longo. Dr. Longo is Plaintiffs' main testing expert, and a testifying expert in the bellwether cases. Dr. Longo tested bottles of Defendants' talc products and claims he found asbestos in the bottles. One court has described Dr. Longo's work as "junk science," concluding that studying "Dr. Longo's testimony reveal[ed] it to be practiced and to employ misdirection and evasiveness. It is at best disingenuous, not credible and unsupported by any respectable community of scientists."¹

¹ (Order Ex. A at 1, 12, *In re Lamar Cty. Asbestos Litig.*, No. 2000-3559 (Tex. Dist. Ct. July 5, 2001) ("*In re Lamar Cty. Order*") (attached as Ex. 1 to the Declaration of Matthew L. Bush, Esq. ("Bush Decl.")).

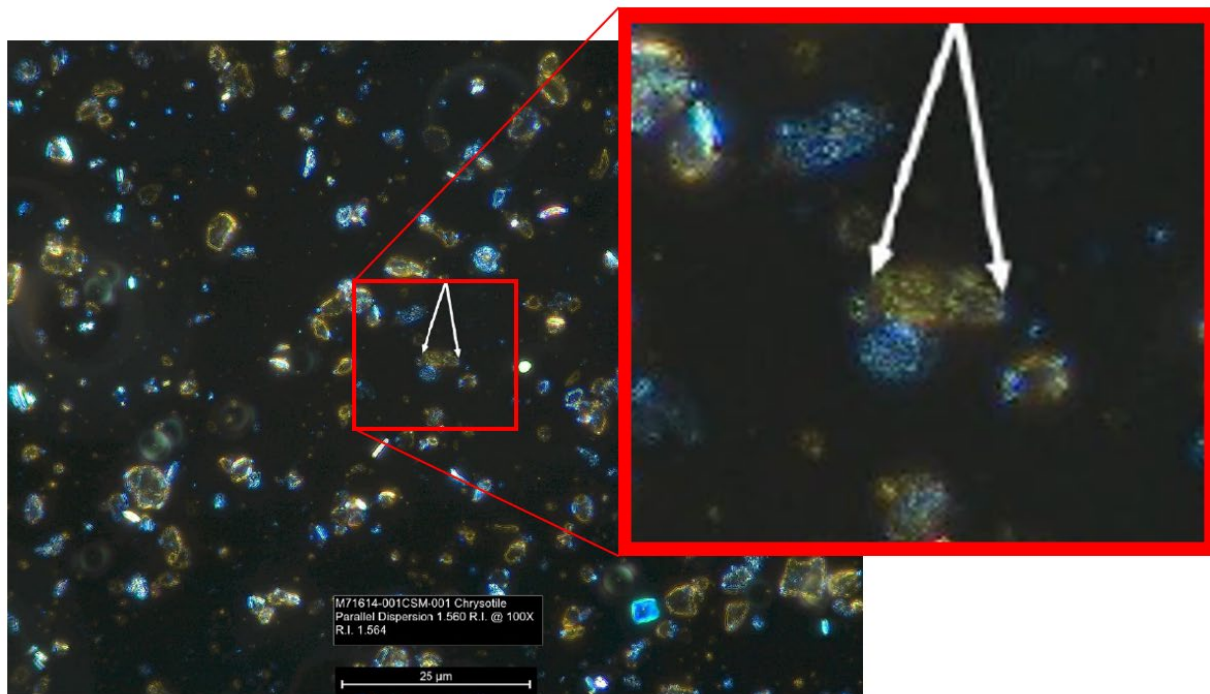
Dr. Longo conducts two types of testing at issue in this motion, both of which should be excluded. He tests for a type of asbestos known as “chrysotile” by polarized light microscopy (“PLM”). And he tests for asbestos in the “amphibole” family of minerals by transmission electron microscopy (“TEM”). (As discussed below, his PLM testing for amphibole asbestos was already excluded in this MDL.)

This Court Should Exclude Dr. Longo’s PLM-Chrysotile Opinions.

In connection with the first round of Rule 702 rulings in this MDL, the Court concluded that “Dr. Longo’s PLM methodology is unreliable because it was replete with subjectivity and reproducibility problems.” *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 155 (D.N.J. 2020). In order to sidestep this decision, Dr. Longo now uses a new PLM method to test talc, but his new method is even worse and more deserving of exclusion than the prior one.

Dr. Longo for years never found chrysotile asbestos in Defendants’ talc products. Shockingly, Dr. Longo now claims to find “chrysotile” by PLM in nearly 100% of bottles of cosmetic talc he tests, regardless of mine source or manufacturer. But even another plaintiffs-side expert in cosmetic talc litigation agrees that what is really going on is that Dr. Longo is simply finding talc in the talc—and calling it chrysotile.

The methodology Dr. Longo employs to allegedly find chrysotile in talc turns on ascertaining the color that various particles appear under a microscope when coated in a particular oil. Talc should appear a pale yellow, and chrysotile asbestos should appear purple. But Dr. Longo is not accurately reporting the color of the particles he examines. For example, Dr. Longo calls the particle below purple, and therefore concludes it is asbestos, even though it is plainly yellow.



What's more, Dr. Longo does not dispute that the other particles surrounding this one he has highlighted in his report are yellow, and as such, indisputably talc. Instead, he just claims this particular particle is somehow a different color than the ones surrounding it. In short, Dr. Longo's PLM-testing depends entirely on an

“Emperor’s New Clothes” methodology: looking at particles that everyone with their own two eyes can see are yellow yet claiming they are, in fact, purple.

Dr. Longo’s excuse to explain why he is claiming to see colors that simply are not there is that one needs to be looking *live down the microscope* in order to be able to verify what he is saying. He testified he could not identify from his imaging whether a particle was talc or asbestos because he would “***have to be looking in the microscope at it to tell you what that is.***”² When asked if his imaging and testimony demonstrated that his “entire analysis is wrong,” he testified: “I stand by this. It’s not wrong.”³ His explanation: “This is chrysotile ***and I would need to be looking at the microscope here.***”⁴ But Plaintiffs opposed Defendants’ request to look down the microscope at the same time as Dr. Longo. That makes Dr. Longo’s PLM testing impossible to verify.

Dr. Longo’s look-down-the-microscope excuse is all the more absurd because he is not the one who actually looked down the microscope. Rather, his analyst, Paul Hess did. As the Special Master concluded, “Hess, not Longo, did the microscopic

² (Dep. of William E. Longo, Ph.D. 55:17-56:14, *Valadez v. Johnson & Johnson*, No. 22-cv-012759 (Cal. Super. Ct. March 3, 2023) (“Longo 3/3/23 *Valadez* Dep.”) (attached as Ex. 2 to Bush Decl.) (emphasis added).)

³ (Tr. 118:20-119:3, *Clark v. Johnson & Johnson*, No. MID-L-003809-18AS (N.J. Super. Ct. May 29, 2024) (“Longo *Clark* Hr’g Vol. I”) (attached as Ex. 3 to Bush Decl.) (emphasis added).)

⁴ (*Id.* (emphasis added).)

analysis required under the PLM methodology.”⁵ Plaintiffs opposed a deposition of Mr. Hess, which the Special Master granted. Then when Mr. Hess’s deposition finally occurred, it was obstructed with *forty* instructions not to answer, including questions as simple as “What color is the particle that you’re calling chrysotile here?”—the key issue.⁶

For all these reasons, Dr. Longo’s PLM-chrysotile testing should therefore be excluded.

This Court Should Exclude Dr. Longo’s TEM-Amphibole Testing.

Dr. Longo’s TEM testing fares no better than his PLM testing. By his own admission, Dr. Longo will ***call something asbestos even when it’s not***. He will call particles asbestos that did not form in the “asbestiform habit” even though that is part of the universal definition of asbestos.

The term “asbestiform” “describes the pattern of growth of a mineral that is referred to as a ‘habit.’”⁷ And as the World Health Organization’s International Agency for Research on Cancer (“IARC”) explains, the term “asbestos” “describes

⁵ ECF No. 32817.

⁶ (Dep. of Paul Hess 78:18-23, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. July 10, 2024) (“Hess MDL Dep.”) (attached as Ex. 4 to Bush Decl.)

⁷ Int’l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 277 (2010) (“IARC 2010 Monograph”) (attached as Ex. 5 to Bush Decl.).

six minerals that occur in the asbestiform habit” and only “when asbestiform, [do] they constitute asbestos.”⁸ Take for example the amphibole mineral tremolite. Asbestiform tremolite is asbestos, and nonasbestiform tremolite is not asbestos. These nonasbestiform versions of amphiboles are often referred to as “cleavage fragments.”⁹

Dr. Longo acknowledges that the “structure [that] comes from breaking apart non-asbestos” minerals does “not magically become, in fact, asbestos.”¹⁰ But he admits he will nevertheless “count it and report it in [his] reports as asbestos,” *even though it is not*.¹¹ Counting particles that are asbestos even when they are not is not a reliable application of the methodology he claims to follow.

Although Dr. Longo’s TEM-testing was not excluded in the first round of Rule 702 decisions, the recent amendments to Rule 702 have changed the landscape. The prior decision rests on bases that those amendments were specifically designed to address. For example, the prior decision concluded that Dr. Longo’s methodology *in the abstract* was reliable, regardless of whether he applied it correctly. *In re J&J*,

⁸ *Id.*

⁹ *Id.*

¹⁰ (Tr. 149:14-17, *Rimondi v. BASF Catalysts LLC*, No. MID-L-2912-17 (N.J. Super. Ct. Law Div. Mar. 5, 2019) (“Longo *Rimondi* Tr. Vol. I”) (attached as Ex. 6 to Bush Decl.)) Drs. Longo and Rigler have issued the same report they did here in numerous other cases, including *Rimondi*.

¹¹ (*Id.* 149:18-20.)

509 F. Supp. 3d at 150 (stating that the courts role was “simply to evaluate whether the *methodology* used by the expert is reliable, *i.e.*, whether, when correctly employed, that methodology leads to testimony helpful to the trier of fact.”) (emphasis in original). But the amendments to Rule 702 clarified that a requirement for admissibility is that the “expert’s *opinion reflects a reliable application* of the principles and methods to the facts of the case.” Rule 702 (emphasis added). Similarly, while the prior decision concluded that deficiencies in the bases for Dr. Longo’s opinion went to weight rather than admissibility, *see In re J&J*, 509 F. Supp. 3d at 149-151, the Committee Notes to the amendments explain that just that type of analysis reflects “an incorrect application of Rules 702 and 104(a),” 2023 Advisory Committee Notes, Rule 702. This Court should exclude Dr. Longo’s TEM-amphibole testing.

This Court Should Exclude Plaintiffs’ Experts’ Asbestos-Causation Opinions

Many of Plaintiffs’ experts attempt to piggyback on Drs. Longo and Rigler’s findings to opine that perineal talc use causes ovarian cancer because it contains asbestos. The studies they rely on at most suggest a weak link between ovarian cancer and heavy occupational exposure to crocidolite asbestos (the most potent form of asbestos). But even Drs. Longo and Rigler only claim to find the most miniscule levels of less potent forms of asbestos in the Defendants’ talc products: ranging down to 3.3 millionths of a percent. Any alleged asbestos exposure from talc

would not remotely resemble the epidemiologic literature on occupational asbestos exposure that Plaintiffs' experts rely on. The experts' "opinion[s]" therefore do not "reflect[] a reliable application of the principles and methods to the facts of the case." Rule 702(d).

This Court Should Exclude Plaintiffs' Experts' Ore Contamination Opinions.

Plaintiffs seek to buttress Drs. Longo and Rigler's report with the opinions of Drs. Mark Krekeler and Robert Cook, two geologists who assert that cherry-picked documents provided to them by plaintiffs' counsel establish that talc deposits used to source defendants' talc products were contaminated with asbestos. But these opinions are inherently unreliable. For one thing, the experts' "research" was limited to a review of documents hand-picked by plaintiffs' counsel and pre-analyzed for them in charts. This is not a scientific methodology. In addition, the experts' opinions are not supported by the data on which they are based. Instead, these materials relate largely to: the mineralogy of geographical regions other than those in which talc for Defendants' products was mined; testing performed on non-talc ore; testing performed on talc *not* used to source the Defendants' products (*i.e.*, industrial talc and talc from other regions); test results that do not identify asbestiform minerals; and test results that were later disavowed or rescinded. Thus, they cannot support Plaintiffs' experts' opinions about asbestos contamination of the Defendants' products.

This Court Should Exclude Plaintiffs' Experts' "Fibrous-Talc" Causation Opinions.

Perhaps sensing weakness in their asbestos theories, many Plaintiffs' experts offer as a backup theory offer the opinion that "fibrous talc" allegedly present in Defendants' products causes cancer. For them, "fibrous talc" just means talc particles that are long and thin. The lynchpin of this opinion is their claim that the International Agency for Research on Cancer ("IARC") classifies "fibrous talc" as a carcinogen under the category of a "Group-1 agent." But IARC does no such thing.

IARC does not even use the term "fibrous talc" at all. Rather, IARC classifies "talc containing . . . *asbestiform fibres*" as a "Group-1 agent."¹² And IARC makes clear that "asbestiform" means a particular way any mineral, including talc, originally formed in nature and does not mean every particle that happens to be long and thin. It specifically says talc particles "may also *be elongated without being asbestiform*."¹³ Lest there be any confusion, IARC describes studies of *Defendants' own talc sources* as studies of non-asbestiform talc and therefore not a Group-1 agent.¹⁴ So there can be no question that Plaintiffs' experts' reliance on IARC is

¹² IARC 2010 Monograph.

¹³ IARC 2010 Monograph at 277 (emphasis added).

¹⁴ IARC 2010 Monograph at 319-320 (listing the Selevan study and Rubino study of Defendants' talc sources as studies of "non-asbestiform talc")

misplaced. In other words, Plaintiffs' experts rely on a flagrant and unsupportable misreading of IARC.

Applying IARC statements that supposedly show that "asbestiform talc" is carcinogenic to the "elongated talc" that Plaintiffs' experts' claim is in Defendants' products does not "reflect a reliable application of the principles and methods to the facts of the case" under Rule 702(d). The very authority Plaintiffs' experts rely on expressly states that those two should *not* be equated and that Defendants' talc does *not* fall into the category of "asbestiform talc."

BACKGROUND

I. Drs. Longo And Rigler

Dr. Longo is the President and a 75% owner of his lab Material Analytical Services, LLC ("MAS").¹⁵ Dr. Rigler, a microbiologist, was MAS's Chief Science Officer.¹⁶ Though Dr. Rigler had a much more limited role related to the talc testing at issue and has since left MAS, he was listed as a co-author of one of the

¹⁵ (Curriculum Vitae of Dr. William E. Longo, Ph.D. (attached as Ex. 7 to Bush Decl.); Tr. 174:7-11, *Leavitt v. Johnson & Johnson*, No. RG17882401 (Cal. Super. Ct. Feb. 7, 2019) ("Longo 2/7/19 *Leavitt* Tr.") (attached as Ex. 8 to Bush Decl.).)

¹⁶ (Curriculum Vitae of Dr. Mark W. Rigler, Ph.D. (attached as Ex. 9 to Bush Decl.).)

earlier MAS reports.¹⁷ Drs. Longo and Rigler ran no tests themselves.¹⁸ The analysts employed at MAS are the ones who tested various samples of Defendants' talcum powder products.

95% of the time that Dr. Longo is in court, he testifying for plaintiffs' attorneys in asbestos litigation.¹⁹ Dr. Longo self-reports that MAS has billed over \$30 million for legal work on behalf of plaintiffs in the last 30 years.²⁰ In fact, as Dr. Longo recently explained, working for plaintiffs in litigation "has allowed our lab to survive."²¹ He believes *every* plaintiffs' attorney in the country discloses him in all of their asbestos lawsuits.²² During this time, Dr. Longo has given somewhere between 2,500 and 3,000 depositions.²³ Dr. Longo generally testifies at

¹⁷ (Second Suppl. Rep. of William E. Longo, Ph.D. and Mark W. Rigler, Ph.D., Feb. 1, 2019 ("Longo 2/1/2019 MDL Rep.") (attached as Ex. 24 to Bush Decl.)).

¹⁸ (Dep. of William E. Longo, Ph.D. 259:19-21, 261:5-8, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. Feb. 5, 2019) ("Longo 2/5/19 MDL Dep.") (attached hereto as Ex. 10 to Bush Decl.); Dep. of Mark W. Rigler, Ph.D. 12:25-13:15; 20:14-19, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. Feb. 6, 2019) ("Rigler MDL Dep.") (attached as Ex. 11 to Bush Decl.).)

¹⁹ (Longo 2/7/19 *Leavitt* Tr. 178:20-23.)

²⁰ (*Id.* 174:22-175:2.)

²¹ (Tr. 1653:19-22, *Olson v. Brenntag N. Am.*, No. 190328 (N.Y. Sup. Ct. Feb. 26, 2019) ("Longo *Olson* Tr.") (attached as Ex. 12 to Bush Decl.).)

²² (Longo 2/7/19 *Leavitt* Tr. 179:3-7.)

²³ (Tr. 171:20-22, *Brick v. Brenntag N. Am., Inc.*, No. BC674595 (Cal. Super. Ct. May 31, 2018) ("Longo *Brick* Tr.") (attached as Ex. 13 to Bush Decl.).)

least once a week, every week.²⁴ 100% of his work to date in talc litigation has been for plaintiffs.²⁵ Courts have excluded Dr. Longo's opinions in other litigations on numerous occasions.²⁶ In some instances they have called his work "junk science" and "pseudo-science at best."²⁷

Dr. Longo has *said* (under oath) that he has tested cosmetic talc only for purposes of litigation, and only began doing so in 2017 after being contacted by

²⁴ (Tr. 3519:10-13, *Allen v. Brenntag N. Am.*, No. DR180132 (Cal. Super. Ct. Oct. 19, 2018) ("Longo 10/19/2018 *Allen* Tr.") (attached as Ex. 14 to Bush Decl.).)

²⁵ (Longo *Olson* Tr. 1646:24-1647:2.)

²⁶ See, e.g., (Rulings on Mots. in Lim., Ex. B at 27-41, *Weirick v. Brenntag N. Am., Inc.*, No. BC656425 (Cal. Super. Ct. Jul. 23, 2018) (attached as Ex. 15 to Bush Decl.); Tr. 886:18-893:25, *Allen v. Brenntag N. Am., Inc.*, No. DR 180132 (Cal. Super. Ct. Oct. 1, 2018) ("10/1/2018 *Allen* Tr.") (attached as Ex. 16 to Bush Decl.)); *In re Lamar Cty. Order* (calling Longo's MAS tests "junk science"); *Krik v. Crane Co.*, 71 F. Supp. 3d 784, 790 (N.D. Ill. 2014); *Suoja v. Owens-Ill., Inc.*, No. 05-CV-219-BBC, 2015 WL 2341436, at *3 (W.D. Wis. May 14, 2015); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *76 (N.D. Ohio June 4, 2010); *In re Garlock Sealing Techs., LLC*, 504 B.R. 71, 80 (Bankr. W.D.N.C. 2014) (finding Dr. Longo's studies "pseudo-science at best"); *Dugas v. 3M Co.*, No. 3:14-CV-1096-J-39JBT, 2016 WL 3946802, at *6 (M.D. Fla. June 21, 2016); *Tyre v. CSC Transp., Inc.*, No. 16-2002-CA-4837, 2003 WL 26474173, at *1-4 (Fla. Cir. Ct. Sept. 24, 2003); *Ball v. Consol. Rail Corp.*, 142 Ohio App. 3d 748, 758-59, 756 N.E.2d 1280, 1288 (Ohio App. 2001); *Grigg v. Allied Packing & Supply Inc.*, No. RG12 629580, 2013 WL 8103870, at *2 (Cal. Super. Ct. Mar. 12, 2013); *In re Asbestos Pers. Inj. Litig.*, No. 03-C-9600, 2009 WL 10696863, at *5 (W. Va. Cir. Ct. Feb. 20, 2009).

²⁷ *In re Lamar Cty. Order*; see also *In re Garlock Sealing Techs.*, 504 B.R. 71, at 80.

plaintiffs' attorneys.²⁸ But back in 2002 before he was hired for this litigation he testified: "[W]e have done our own studies on talc, but what I haven't been able to do is find a cosmetic where I can say, yes, that has asbestos in it."²⁹ He said then that he was "very familiar" with the issue and that cosmetic talc containing asbestos was "an urban legend."³⁰

II. Dr. Longo and Dr. Rigler's Testing

"Asbestos" is a collective term describing a group of six minerals that, under certain rare geological conditions, can form in bundles composed of long, thin, extremely flexible fibers.³¹ Of these, five fall into the "amphibole" mineral family, and one (chrysotile) falls in the serpentine mineral family.

²⁸ (Longo 2/7/19 *Leavitt* Tr. 170:24-171:6; Dep. of William E. Longo, Ph.D. 35:2-36:16, *Herford v. AT&T*, No. BC646315 (Cal. Super. Ct. Aug. 23, 2017) ("Longo *Herford* Dep. Vol. I") (attached as Ex. 17 to Bush Decl.); Tr. 1841:26-1842:15, *Anderson v. Borg-Warner Corp.*, No. BC666513 (Cal. Super. Ct. May 15, 2018) (attached as Ex. 18 to Bush Decl.).)

²⁹ (Dep. of William E. Longo, Ph.D. 155:20-23, *Starkweather v. ACandS, Inc.*, No. 00-6030 (Mass. Super. Ct. July 18, 2002) (attached as Ex. 19 to Bush Decl.).)

³⁰ (*Id.* 155:10-17; *see also* Dep. of William E. Longo, Ph.D. 106:11-19, *In re Kelvin Manbodh Asbestos Litig.*, No. 324/1997 (V.I. Terr. Ct. May 28, 2002) (attached as Ex. 20 to Bush Decl.) ("We've looked. We have not found it."))

³¹ *E.g.*, Perkins & Harvey, U.S. Env't'l Protection Agency, *Test Method: Method for the Determination of Asbestos in Bulk Building Materials A-1* (1993) ("EPA R-93") (attached as Ex. 21 to Bush Decl.); Int'l Org. for Standardization, *Ambient Air – Determination of asbestos fibres – Direct-transfer transmission electron microscopy method 2* (1995) (attached as Ex. 22 to Bush Decl.); IARC 2010 Monograph at 277; Nat'l Inst. for Occupational Health and Safety, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap*

A. MAS originally only detected amphiboles.

For years, MAS only detected amphiboles in Defendants' talc products. In the original round of expert reports in this MDL, Dr. Longo and Dr. Rigler submitted (after some amendments) a February 1, 2019 report designated the "2nd Supplemental Report."³² That report included testing of 49 relevant samples from bottles of the Johnson's Baby Powder and Shower to Shower.³³ These examples all came from the Johnson & Johnson archive and were split pursuant to a protocol created for this MDL.

Drs. Longo and Rigler purported to find only miniscule amounts of what they claim is amphibole "asbestos" in 32 of the 49 relevant samples they tested. The percentage of asbestos by weight they report ranges from .0092% at the high end (9.2 *thousandths* of a percent) to .0000033% (3.3 *millionths* of a percent) at the low end.³⁴ Their median bottle was .000017%.³⁵

for Research 7-8 (2011) ("NIOSH Roadmap") (attached as Ex. 23 to Bush Decl.); 30 C.F.R. § 56.5001(b)(1).

³² (Second Suppl. Rep. of William E. Longo, Ph.D. and Mark W. Rigler, Ph.D., Feb. 1, 2019 ("Longo 2/1/2019 MDL Rep.") (attached as Ex. 24 to Bush Decl.)).

³³ Seven of the 56 samples contained Korean talc, which is unlikely to have been in products used by plaintiffs in the MDL, and these samples are therefore excluded from the analysis. (Although Dr. Longo's report states that 57 bottles were tested, the underlying data only reveal 56.)

³⁴ (Dep. of William E. Longo, Ph.D. 126:1-12, *Weirick v. Brenntag N. Am.*, No. BC656425 (Cal. Super. Ct. Apr. 17, 2019) ("Longo 4/17/19 *Weirick* Dep.") (attached as Ex. 25 to Bush Decl.); Longo 2/1/2019 MDL Rep. at 33, 41.)

³⁵ (Longo 4/17/19 *Weirick* Dep. 126:13-24; Longo 2/1/2019 MDL Rep. at 36.)

In over half of the 49 samples (27 of them), the analysts employed by Drs. Longo and Rigler detected only 0 or 1 *particle* they claim to be asbestos. In the median bottle, they detected only a single particle. Drs. Longo and Rigler then extrapolated from those miniscule amounts to estimate the amount of particles per gram in the bottle as a whole. That is why whether or not Dr. Longo and Dr. Rigler are identifying even single particles correctly is so critical. With respect to the median bottle, for example, if the sole particle of “asbestos” Drs. Longo and Rigler found was in fact not asbestos, they would be forced to conclude that they found no evidence of asbestos contamination in that bottle.

In that original testing, MAS tested the samples using two different types of microscopes: transmission electron microscopy (“TEM”) and “polarized light microscopy” (“PLM”). MAS never found any chrysotile in any of the samples in the February 1, 2019 report. And this Court excluded his PLM methodology. Dr. Longo then began pursuing a new method of PLM testing.

B. Dr. Longo finds chrysotile in nearly 100% of samples with a new PLM method.

In early 2020, Dr. Longo testified to the FDA that he had “cracked the code” for testing talc for chrysotile asbestos using PLM.³⁶ He then proceeded to issue

³⁶ (Tr. 176:19-177:5, *U.S. Food and Drug Admin. Mtg: Testing Methods for Asbestos in Talc and Cosmetic Prods. Containing Talc*, Feb. 4, 2020 (“Longo 2/4/2020 FDA Tr.”) (attached as Ex. 26 to Bush Cert)).

numerous reports in the state court cosmetic talc litigation which set out the results of MAS's testing of Defendants' talc products using his new PLM method. Now, as a matter of course, each time Dr. Longo issues a report in any individual case, it becomes part of the body of work that Dr. Longo relies on going forward in each subsequent case. When the second round of expert reports were exchanged in this MDL, Dr. Longo submitted an updated 4th Supplemental Report.³⁷ By this time, Dr. Rigler had left MAS.

As that report makes clear, Dr. Longo did not test (and has never tested) with his new PLM methodology the samples from the J&J archive that were the subject of his original MDL report. Instead, Dr. Longo's current MDL report incorporates his state court litigation reports issued between the time of the prior Rule 702 decision and his most recent deposition in this matter.³⁸

As discussed in more detail below, Dr. Longo relies on a PLM method he created that by his own admission is not ready to be published. Using this method, he now conveniently finds chrysotile in nearly 100% of talc samples he tests—regardless of the manufacturer or mine source.³⁹ He says that “[a]ny bottle that was

³⁷ (Report of William E. Longo, Ph.D., Apr. 29, 2024 (“Longo 4/29/2024 Rep.”) (attached as Ex. 27 to Bush Decl.).)

³⁸ (*Id.* at 2.)

³⁹ (Dep. of William E. Longo, Ph.D. 138:9-18, *Forrest v. Johnson & Johnson*, No. 1522-CC00419-02 (Mo. Cir. Ct. Feb. 8, 2021) (“Longo 2/8/2021 *Forrest*

sold in North America that used a mine source for cosmetic talc in North America will have some level of asbestos in it.”⁴⁰

This, despite previously testifying that “the PLM method is not appropriate to do an evaluation for these types of products” (*i.e.*, talcum powder products).⁴¹ In fact, Dr. Longo testified at least as of January 2019 that he had never “personally analyzed a [talc] sample for the presence of asbestos using PLM.”⁴² As he put it then, “I don’t do PLM analysis.”⁴³

Dep.”) (attached as Ex. 28 to Bush Decl.); *see also* Chart showing 125 positives of 125 tests (attached as Ex. 29 to Bush Decl.).)

⁴⁰ (Dep. of William E. Longo, Ph.D. 449:12-21, *Eagles v. Arvinmeritor, Inc.*, No. 22-CV-018294 (Cal. Super. Ct. Nov. 3, 2023) (“Longo *Eagles* Dep. (Vol. III)”) (attached as Ex. 30 to Bush Decl.).)

⁴¹ (Tr. 2921:25-28, *Weirick v. Brenntag N. Am., Inc.*, No. BC656425 (Cal. Super. Ct. Aug. 24, 2018) (“Longo 8/24/18 *Weirick* Tr.”) (attached as Ex. 31 to Bush Decl.).)

⁴² (Dep. of William E. Longo, Ph.D. 85:18-20, *Young v. Johnson & Johnson*, No. 1522-CC09728-02 (Mo. Cir. Ct. Jan. 25, 2019) (“Longo *Young* Dep.”) (attached as Ex. 32 to Bush Decl.).)

⁴³ (*Id.* 86:5-6.)

ARGUMENT

I. This Court Should Exclude Dr. Longo's Chrysotile-PLM Opinions.

Under the PLM method that Dr. Longo uses, the mineral type of a particle is determined by identifying the color that the particle appears under the microscope after coating it in a particular oil.⁴⁴

For his new PLM work, Dr. Longo first used an Olympus-brand microscope, (including when he told the FDA he “cracked the code” on identifying chrysotile in talc.)⁴⁵ But what he was calling “talc” and “asbestos” were both the same color meaning there was no way to reliably distinguish between the two (and the talc did not even appear as the color it is supposed to look under a PLM).⁴⁶ Defense experts criticized Dr. Longo's work for not being appropriately “white balanced” and therefore not faithfully depicting the colors of the particles.⁴⁷ That led Dr. Longo to acknowledge that he was using a microscope with a tungsten lightbulb which emitted

⁴⁴ (See Tr. 279:3-5, *Clark v. Johnson & Johnson*, No. MID-L-003809-18AS (N.J. Super. Ct. May 30, 2024) (“Longo *Clark* Hr'g Vol. II”) (attached as Ex. 33 to Bush Decl.); Longo *Forrest* Dep. 72:15-17, 75:23-76:9.)

⁴⁵ (Dep. of William E. Longo, Ph.D. 194:17-195:1, *Clark v. Johnson & Johnson*, (N.J. Super. Ct. April 2, 2024) (“Longo 4/2/2024 *Clark* Dep. (Vol. II)”) (attached as Ex. 34 to Bush Decl.) (emphasis added).)

⁴⁶ (Longo 3/3/23 *Valadez* Dep. 32:15-33:1; Longo 3/3/23 *Valdez* Dep. Ex. 4, “Chrysotile PLM Dispersion Staining Colors” (attached as Ex. 111 to Bush Decl.).)

⁴⁷ (Dep. of William E. Longo, Ph.D. 32:22-36:15, *Bonnem v. Walgreen, Co.*, No. 20-L-12414 (Sept. 17, 2021) (“Longo *Bonnem* Dep.”) (attached as Ex. 35 to Bush Decl.); *see also* (Linda Zimmerman's JBP Containers, William E. Longo, Ph.D., Feb. 24, 2020 (“Longo 2/24/2020 Zimmerman Rep.”) (attached as Ex. 112 to Bush Decl.)).

a yellow/orange-hued light that distorted the color of his imaging—the key component of identifying the mineral.⁴⁸

Dr. Longo’s analyst Paul Hess who actually conducted the testing admitted that he did not “recall ever dealing with” a blue-light or daylight filter on the Olympus microscope to normalize the colors even though that is required under the ISO 22262-1 method that MAS purports to follow.⁴⁹ Dr. Longo no longer uses the microscope with that lightbulb, but rather a Lecia brand microscope.

Additionally, defense expert Dr. Shu-Chun Su prepared a report in the state court litigation in 2022 explaining that Dr. Longo should be using a different type of oil (which also affects the color of the particles).⁵⁰ As a result, Dr. Longo changed the oil he used.⁵¹

With these color distortions corrected, Dr. Longo has been forced into a corner. Now he is calling yellow particles “purple” and claiming that the only way to verify that plainly incorrect reporting of the color is to look live down the microscope, which Plaintiffs have refused to let Defendants do.

⁴⁸ (Longo 3/3/23 *Valadez* Dep. 30:9-31:3.)

⁴⁹ (Hess *MDL* Dep. 68:3-7; *see also id.* at 65:5-11 (similar).); ISO 22262-1 at 15, 25 (attached as Ex. 36 to Bush Decl.).

⁵⁰ (Report of Dr. Shu-Chun Su, “Talc Misidentified as Chrysotile,” Jan. 30, 2022 (attached as Ex. 37 to Bush Decl.).)

⁵¹ (Longo 3/3/23 *Valadez* Dep. 15:3-18.)

Judge Wolfson already excluded Dr. Longo's PLM analysis in the context of his amphibole testing. Dr. Longo's new PLM analysis suffers from all the same flaws, and this Court need do no more than simply adhere to the prior PLM decision. *See infra* § A. Yet even if this Court were to examine Dr. Longo's method further, that new method suffers from additional flaws rendering it even *more* unreliable than the original method that was excluded. *See infra* § B. Either way, this Court should preclude Dr. Longo's new PLM testing.

A. Judge Wolfson's prior Rule 702 reasoning excluding Dr. Longo's PLM analysis applies to Dr. Longo's new PLM method.

Previously, Dr. Longo attempted to use PLM to identify purported amphibole asbestos in Defendants' talc products. Judge Wolfson excluded those opinions under Rule 702, holding that any "results derived from the PLM testing" were inadmissible. *In re Johnson & Johnson Talcum Powder Products Mktg., Sales Practices & Products Litig.*, 509 F. Supp. 3d 116, 154 (D.N.J. 2020). Judge Wolfson gave three reasons for her decision; each is as true today as it was back then.

First, Judge Wolfson criticized the way Dr. Longo attempted to use ISO 22262-1 methodology to quantify asbestos levels. ISO 22262-1 itself states that "it is recognized that the accuracy and reproducibility of" its quantifications of asbestos content "is very limited."⁵² Accordingly, ISO 22262-1 states that when the asbestos

⁵² ISO 22262-1 at vi.

concentration found is between 0% and 5% and “it is necessary to make critical decisions on the basis of the results” (including a result of “non-detected”) then ISO 22262-2 should be used.⁵³ Dr. Longo is claiming to find asbestos concentrations lower than 0.1%; usually far lower. Dr. Longo *still* uses the ISO 22262-1 method for his new PLM-chrysotile analysis to quantify levels of asbestos at similarly low levels.⁵⁴

Second, Judge Wolfson found that Dr. Longo’s testimony was unreliable because it was “replete with subjectivity and reproducibility problems.” The analysis was subjective because “the quantity of asbestos in the samples was determined by visual examination ‘based on past standards, based on petrographic that show what the various percentages are.’” *In re Johnson & Johnson Talcum Powder Products Mktg., Sales Practices & Products Litig.*, 509 F. Supp. 3d at 155 (quoting Longo Daubert Hr’g Tr., at 611-13). “These standards (weight percentages) were generated by MAS and were not produced to Defendants,” which made “replication of Dr.

⁵³ *Id.* at 35 n.1.

⁵⁴ (See Dep. of William E. Longo, Ph.D. 26:10, *Prudencio v. Johnson & Johnson*, No. RG20061303 (Cal. Super. Ct. April 21, 2021) (“Longo *Prudencio* Dep. (Vol. 1)”) (attached as Ex. 38 to Bush Decl.) (“[The] analysis follows the ISO 22262-1 methodology”); *see also, e.g.*, Report of William E. Longo, Ph.D. at 4, Feb. 28, 2023 (“Longo 2/28/23 Rep.”) (attached as Ex. 39 to Bush Decl.).)

Longo's testing is difficult." *Id.* Because without that information "reproducing Dr. Longo's test under the PLM would not be possible," "the testing is unreliable."⁵⁵ *Id.*

MAS still uses the same methodology Judge Wolfson excluded. Analysts in Dr. Longo's laboratory "look at the size of the chrysotile structures and then they will look at the area of where it sits, and then they will *make an estimate . . . it's a visual estimate* of how much area that chrysotile is taking up."⁵⁶ Dr. Longo admits this is a "visual estimate, not a visual calculation," and each visual estimate is based on that individual's experience.⁵⁷

"It's literally [the individual's] opinion about the range that he's looking at on the slide."⁵⁸ Each assessment is an isolated review without reference points.⁵⁹ Miraculously, Dr. Longo claims just by his own say-so that his analysis can accurately estimate down to *10,000th of a percentage point* with an error rate of only

⁵⁵ Dr. Longo at times attempts to calculate a "fiber per gram" quantification for his new PLM results. He does not identify any standardized protocol he is following for those quantifications. And more importantly, for nearly every test, he did not provide the backup data or calculations demonstrating how he arrived at those amounts. These new fiber per gram estimates therefore do not alter the analysis.

⁵⁶ (See Longo 4/2/2024 *Clark Dep.* Vol. II 183:21-184:1.)

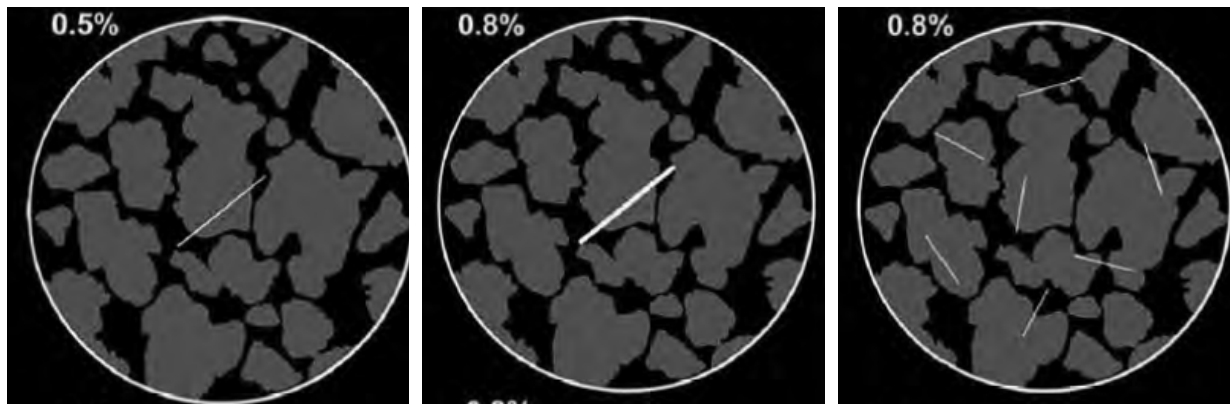
⁵⁷ (*Id.* 184:15-23.)

⁵⁸ (*Id.* 185:5-6.)

⁵⁹ (*Id.* 187:11-188:12.)

.005% based solely on this visual estimation with no reference point for comparison.⁶⁰

For example, these images represent the difference between a particle taking up 0.5% and 0.8% of the visual field (i.e. a 0.3% difference)⁶¹:



Yet Dr. Longo claims to be able to quantify percentages as low as 0.0008%.⁶² Purely subjective measurements to this degree of “precision” defy logic and are performe unreliable.

Third, Judge Wolfson recognized that Dr. Longo’s PLM findings had not been reproduced by others, despite at least one attempt. The Court noted that “Dr. Longo requested Dr. Lee Poye of J-3 Laboratory (‘J-3’) to perform a PLM analysis using the same ISO 22262-1 method on 22 of the historical talc samples,” but “J-3’s PLM analysis was negative for asbestos for each sample.” *In re Johnson & Johnson*

⁶⁰ (*Id.* 184:24-185:19; *see also* Report of Dr. Shu-Chun Su, May 21, 2024 (“MDL Su Rep.”) at 10-11, Ex. C at 53-64.) (attached as Ex. 107 to Bush Decl.).)

⁶¹ (MDL Su Rep., Ex. C at 59).

⁶² (Longo 4/29/2024 Rep. at 24 (Table 7, Row 6).)

Talcum Powder Products Mktg., Sales Practices & Products Litig., 509 F. Supp. 3d 116, 155 (D.N.J. 2020). “Dr. Longo had no explanation,” which “underscores the very real reliability and reproducibility issues plaguing Dr. Longo’s PLM testing.” *Id.*

Again, the same is still true. Dr. Longo tested 18 Chinese talc ore samples (the talc used for years in JBP) using his new PLM method. Dr. Longo found chrysotile in all 18 of the 18 samples.⁶³ Those same samples were also tested by Dr. Steven Compton—a plaintiff-side expert in the cosmetic talc litigation (though not in this MDL). Dr. Compton used TEM, which is the more sensitive microscope.⁶⁴ Yet Dr. Compton found *no chrysotile* in any of the same 18 samples.⁶⁵

The Court need not look beyond Judge Wolfson’s prior opinion to exclude Dr. Longo’s PLM analysis as unreliable and inadmissible.

B. Dr. Longo’s new PLM analysis is even more flawed than the previously excluded method.

While this Court can and should exclude Dr. Longo’s new PLM method based on Judge Wolfson’s prior opinion, his new analysis suffers from numerous

⁶³ (Report of William E. Longo, Ph.D., Oct. 8, 2010 at 12, 22-23 (“Longo 10/8/2020 Rpt.”) (attached as Ex. 40 to Bush Decl.).)

⁶⁴ (Tr. 177:24-178:5, *Hayes v. Colgate-Palmolive Co.*, No. 16-CI-03503 (Ky. Cir. Ct. July 23, 2019) (“Longo Hayes Tr.”) (attached as Ex. 41 to Bush Decl.).)

⁶⁵ (Report of Steven P. Compton, Ph.D., Sept. 24, 2020 at 3 (“Compton 9/24/2020 Rep.”) (attached as Ex. 42 to Bush Decl.).)

additional flaws, rendering it even *more* unreliable than in the first round of Rule 702 rulings.

Dr. Longo has previously testified that a different method—transmission electron microscopy or “TEM”—is the best way to accurately identify chrysotile in talc.⁶⁶ In fact, he testified that using TEM would make it “fairly simple to tell whether or not you are, in fact, looking at chrysotile as opposed to talc.”⁶⁷ TEM provides “direct information about crystal structure and chemistry” of the particles which if faithfully applied would be able to objectively distinguish talc from chrysotile” without relying on color.⁶⁸ Yet Dr. Longo has refused to test the validity of his PLM work by using TEM.⁶⁹

There are five independent reasons to exclude Dr. Longo’s new PLM testing. *First*, Dr. Longo’s method fails the traditional Rule 702 factors. The method is not testable, it has not been subject to peer review, it has no known rate of error, does not have standard operating procedures, is not generally accepted, and has not been used outside of litigation.

⁶⁶ (See Dep. of William E. Longo, Ph.D. 187:19-188:17, *Kerkhof v. Brenntag N.A., Inc.*, No. 439392-V (Cir. Ct. Nov. 5, 2018) (“Longo *Kerkhof* Dep.”) (attached as Ex. 43 to Bush Decl.).

⁶⁷ (Longo *Clark* Hr’g Vol. 1 42:10-14.)

⁶⁸ (Longo *Clark* Hr’g Vol. II 279:6-12.)

⁶⁹ (Longo 4/2/2024 *Clark* Dep. Vol. II 206:7-11.)

Second, even though identifying the mineral depends on ascertaining the color of the particle, MAS misreports the colors of the particles. MAS takes particles that are plainly yellow and calls them purple for purposes of the analysis. That alone is sufficient to exclude the analysis.

Third, Dr. Longo's excuse for calling yellow particles purple is that the particles somehow look different when viewing them under the microscope at his lab. But that renders the methodology impossible to independently verify since the samples quickly degrade (and are discarded) and Plaintiffs rebuffed Defendants' efforts to look at the same particles with the same microscope at the same time at Dr. Longo's lab to test Dr. Longo's assertions. His analysis should be excluded because it is impossible to verify. It is still true that "Dr. Longo's PLM methodology is unreliable because it was replete with subjectivity and reproducibility problems. *In re J&J*, 509 F. Supp. 3d at 155.

Fourth, although Dr. Longo claims the only way to verify his results is to look down the microscope, he is not even the one looking down the microscope. That's done by his analyst, Paul Hess. Mr. Hess is the one making all the critical decisions such as reporting what color he's seeing and whose judgment is truly at issue. *See In re Zantac*, 644 F. Supp. 3d at 1136 ("The expert cannot vouch for the assistants' judgment where the soundness of that judgment is at issue."). Worse, the deposition of Mr. Hess was obstructed by persistent instructions to not answer

even the most basic questions. Plaintiffs have set up their experts so that Dr. Longo is relying on Mr. Hess's judgment, but then Mr. Hess is prevented from being subject to cross examination. This serves as yet another reason to exclude Dr. Longo's opinions.

Finally, even if the colors Dr. Longo reports were correct, those colors serve as an input to yet another flawed calculation called a "birefringence calculation" which helps determine the mineral type. Dr. Longo's testing should be excluded for the additional reason that he does not adhere the methodology he claims to follow. His improper method makes the results of the calculation more closely resemble what the results should look like for chrysotile rather than talc.

1. Dr. Longo's PLM methodology should be excluded because it fails the longstanding Rule 702 factors.

Dr. Longo's PLM-chrysotile methodology fails the longstanding Rule 702 factors miserably. The method does not "consist[] of a testable hypothesis" because—as discussed above—he claims the only way to verify his work is to look live down his microscope which defense experts are not able to do. *See In re Paoli R.R. Yard PCB Litig. ("Paoli II")*, 35 F.3d 717, 742 n.8 (3d Cir. 1994).

The method has not "been subject to peer review." *See id.* Worse, Dr. Longo testified that his PLM methodology is not even *ready* to be published in a peer-

reviewed journal.⁷⁰ He is therefore by definition not employing “in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). In fact, Dr. Longo has even disagreed that “submitting [his] methods to the scrutiny of the larger scientific community is a component of good science.”⁷¹ *See also In re Zantac (Ranitidine) Prod. Liab. Litig.*, 644 F. Supp. 3d 1075, 1094 (S.D. Fla. 2022) (“A common refrain in *Daubert* jurisprudence is that ‘law lags science,’ because the courtroom is not the appropriate forum for new scientific methodologies and theories to be tested; laboratories and published journals are the appropriate forum.”).

Dr. Longo’s work has no “known or potential rate of error.” *See Paoli II*, 35 F.3d at 742 n.8. Dr. Longo does not “know the rate of error of MAS’s PLM chrysotile method” and has not done “any sort of analysis” of the “rate of error in connection with the PLM chrysotile method MAS uses.”⁷²

⁷⁰ (Dep. of William E. Longo, Ph.D. 118:5-119:7, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. May 2, 2024) (“Longo MDL (Vol. I) Dep.”) (attached as Ex. 45 to Bush Decl.); *see also* Dep. of William E. Longo, Ph.D. 607:5-15, *Chapman v. Avon Prods.* (Oct. 3, 2022) (“Longo Chapman Dep.”) (attached as Ex. 44 to Bush Decl.) (agreeing in 2022 his method was still in the “beta phase”).)

⁷¹ (Longo MDL (Vol. I) Dep. 124:16-24.)

⁷² (Dep. of William E. Longo, Ph.D. 320:15-22, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. May 3, 2024) (“Longo MDL (Vol. II) Dep.”) (attached as Ex. 48 to Bush Decl.).)

Dr. Longo's methodology also fails the factor of "the existence and maintenance of standards controlling the technique's operation." *See Paoli II*, 35 F.3d at 742 n.8. He testified that he has not "finished the standard operating procedures" for his method.⁷³

The method has also not been "generally accepted." *See Paoli II*, 35 F.3d at 742 n.8. No one else on the planet is using Dr. Longo's method, and no one has been able to find chrysotile by PLM despite Dr. Longo claiming to find chrysotile nearly 100% of the time. And no one who has reviewed MAS's imaging has been willing to go on record to agree that MAS is finding chrysotile by PLM.⁷⁴ Dr. Longo's lab is on an island of its own.

Dr. Longo does not have "the qualifications of the expert witness testifying based on the methodology." *See Paoli II*, 35 F.3d at 742 n.8. He has not taken any courses in PLM, describes himself as "self-taught," and previously testified that PLM should *not* be used to test talc for the presence of asbestos. Worse, Defendants were obstructed from fully examining Paul Hess—the person at MAS who has PLM experience who actually conducts the analysis.

Finally, there are no "non-judicial uses to which the method has been put." *See Paoli II*, 35 F.3d at 742 n.8. Dr. Longo's new PLM analysis is entirely made-

⁷³ (Longo *MDL* (Vol. I) Dep. at 47:6-13.)

⁷⁴ (Longo *MDL* (Vol. 1) Dep. 122:16-123:12.)

for-litigation. For all these reasons, this Court should exclude Dr. Longo's chrysotile-PLM testing.

2. Dr. Longo's PLM methodology should be excluded because MAS misreports the colors of the particles.

Dr. Longo's PLM analysis should be excluded because he misreports the colors of the particles he sees—which is what the analysis turns on.

Under the PLM method that Dr. Longo uses, the mineral type of a particle is determined by identifying the color that the particle appears under the microscope after coating it in a particular oil.⁷⁵ Put simply: The analysis is “based on color.”⁷⁶ More specifically, PLM analysis performed at MAS relies on analysts correctly identifying the specific shade of color seen under the microscope, matching those colors up to a chart, and then reporting values that are used to identify whether the microscopic particles viewed are asbestos, talc, or some other mineral.⁷⁷

So, for example, the ISO (International Standards Organization) protocols that Dr. Longo claims at least in part to follow state that talc in parallel orientation⁷⁸

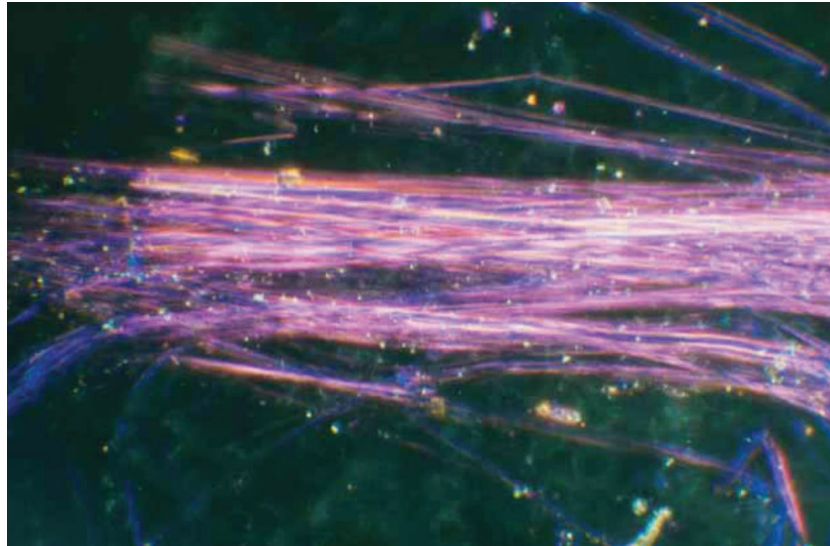
⁷⁵ (See Longo *Forrest* Dep. 72:15-17, 75:23-76:9.)

⁷⁶ (Tr. 279:3-5, Longo *Clark* Hr'g Vol. II.)

⁷⁷ (Tr. 48:9-49:1, 113:12-18, Longo *Clark* Hr'g Vol. I.)

⁷⁸ Particles are evaluated by PLM in both a “parallel” and “perpendicular” orientation, with each producing a different color.

should be a pale yellow.⁷⁹ Chrysotile asbestos, by contrast, should generally appear purple in parallel. Below is an image of a reference sample for chrysotile from the ISO protocols⁸⁰:



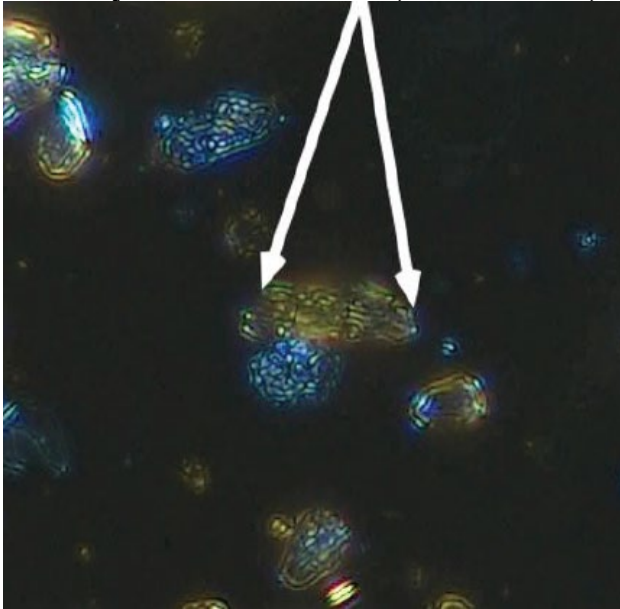
Dr. Longo is taking particles that are plainly yellow (the color talc should appear) and calling them purple (the color chrysotile asbestos should appear). This does not reflect a reliable application of the methods he purports to use to this case. *See* Rule 702(d).

Take for example this particle below:

⁷⁹ ISO 22262-1 at 28; (Dep. of William E. Longo, Ph.D. 245:5-17, *Eagles v. Arvinmeritor, Inc.*, No. 22-CV-018294 (Cal. Super. Ct. Oct. 23, 2023) (“Longo *Eagles* Dep. (Vol. II)”) (attached as Ex. 46 to Bush Decl.).)

⁸⁰ ISO 22262-1 at 43, Figure D.3 (chrysotile in parallel orientation).

**Dr. Longo's Claimed
"Chrysotile" Asbestos (Ex. 39 at 33)**



**Dr. Longo's
Claimed Color**

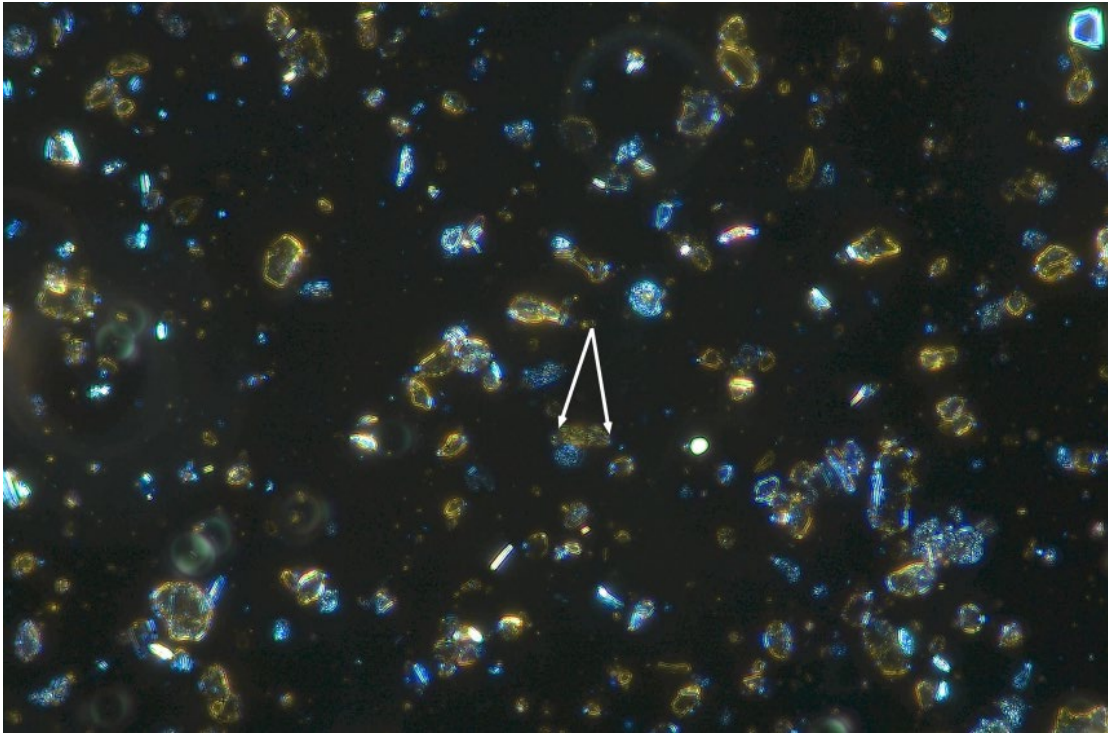


Dr. Longo admitted that particle is “brownish gold.”⁸¹ (Talc should appear yellow.) However, Dr. Longo treats that particle as the purple color depicted on the right for purposes of his analysis—i.e. the color chrysotile should look like.⁸²

Indeed, Dr. Longo is claiming that the particle above is somehow a different color than all the other yellow particles of talc that surround it:

⁸¹ (Longo *Eagles* Dep. (Vol. II) 263:5-18.)

⁸² (Longo *Eagles* Dep. (Vol. III) 308:4-309:7.) Dr. Longo’s analyst reports a numerical “refractive index” or “R.I.” for the color of the particle he claims to see. Those indices correspond to particular colors. Dr. Longo’s report lists this particle as R.I. 1.564, which corresponds to a purple of 560 nanometers depicted above. (Longo *Valadez* Rep. at 33; Tr. 48:9-49:1, 113:12-18, Longo *Clark* H’rg Vol. 1; see also R.I. Value Demonstrative (attached as Ex. 47 to Bush Decl.).)



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Dr. Longo has argued the reason he was treating the particles as purple was because he was relying on the color seen around the edge the particle.⁸⁴ However, Dr. Longo admits that edge colors of the type he is now relying on can be an artifact of his images, for example if the “focus is off.”⁸⁵ Dr. Longo’s analyst Paul Hess who actually performed the analysis also agreed that “one way that you can get these types of edges around particles” is the “focus.”⁸⁶

⁸³ (Longo 2/28/23 Rep. at 33.)

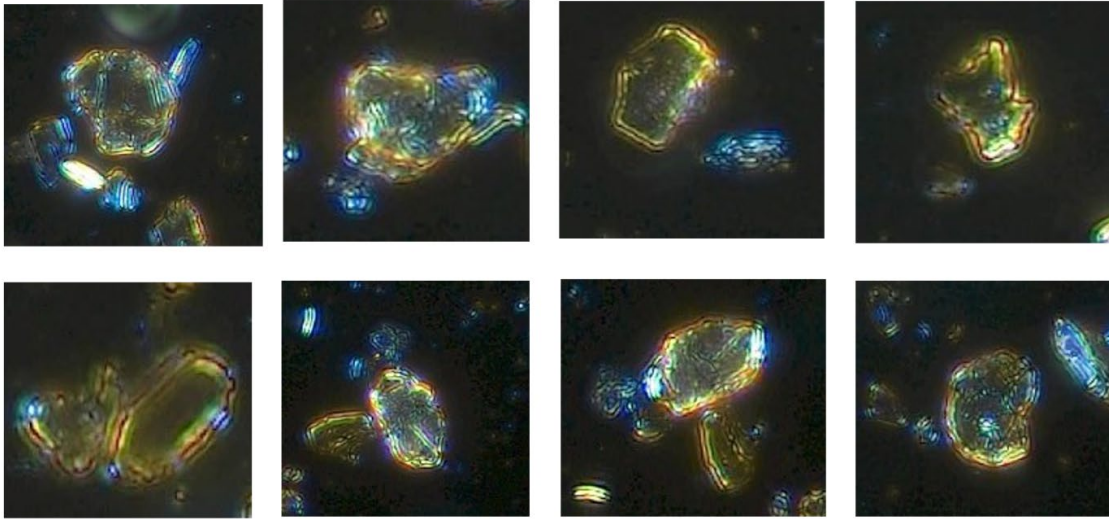
⁸⁴ (See Longo 3/3/23 Valadez Dep. 62:23-63:8.)

⁸⁵ (Longo *Eagles* Dep. Vol. II 256:21-257:3 (“[E]very particle has some of the red around it. And I don’t know if that’s just an artifact or not.”).) Mr. Hess was instructed not to answer whether the edge coloring he is relying on to identify particles as “chrysotile” is present on the talc particles as well. (Hess *MDL* Dep. 128:10-129:2).

⁸⁶ (Hess *MDL* Dep. 129:4-16.)

Indeed, the same red/purple edges can also routinely be seen around talc plates that Dr. Longo has never claimed are chrysotile.⁸⁷

Edge Effect On Talc Plates



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In other words, any red or purple color around the edges of particles is present on both talc particles and the particles Dr. Longo claims are chrysotile. So, it cannot be used to distinguish between the two. *See, e.g. In re Zantac*, 644 F. Supp. 3d at 1127 (excluding an expert for failing to explain who one “chromatogram” showed the presence of NDMA while another did not when they looked identical). That Dr. Longo does not even know if that edge effect that he relies on is simply an artifact of his imaging technique renders this “edge” excuse doubly unreliable.

⁸⁷ (Longo 2/28/23 Rep. at 33, 34, 38, 39.)

In short: the only way the PLM method that Dr. Longo claims to rely on can be reliably applied to the facts is to faithfully report the colors of the particles. As Dr. Longo admits, the PLM method he selected “depend[s] on whether [the] analyst in [the] lab accurately picked the right color for the analysis.”⁸⁸ But Dr. Longo takes particles that are yellow and calls them purple. That represents a fundamental misapplication of a critical step in the analysis. This flaw does not simply go to the “weight” of his testimony and is not relegated merely to cross-examination at trial. Dr. Longo’s opinion does not “reflect[] a reliable application of the principles and methods to the facts of the case.” Rule 702(d).

Even Dr. Shu Chun Su, the author of part of the methodology Dr. Longo claims to rely on, agrees.⁸⁹ Dr. Longo has testified that Dr. Su is a “well respected scientist,” “an authority in terms of mineral identification through staining techniques,” and that essentially “every lab in the country” uses Dr. Su’s methods for their PLM analysis.⁹⁰ Dr. Su—a defense expert in this MDL—concluded that among the many “systematic and chronic deficiencies” in Dr. Longo’s analysis is

⁸⁸ (Tr. 287:10-14, Longo *Clark Hr’g* Vol. II.)

⁸⁹ (Dep. of William E. Longo, Ph.D. 229:21-25, *Reyes v. Johnson & Johnson*, No. RG20052391 (Cal. Super. Ct. Sept. 25, 2020) (“Longo *Reyes* 09/25/2020 Dep.”) (attached as Ex. 49 to Bush Decl.); (Tr. 5133:11-19; 5146:23-5147:7, *Prudencio v. Johnson & Johnson*, No. RG20061303 (Cal. Super. Ct. July 7, 2021) (“Longo *Prudencio* 7/7/2021 Tr.”) (attached as Ex. 50 to Bush Decl.).)

⁹⁰ (Longo *Prudencio* 7/7/2021 Tr. 5133:11-5134:11.)

the “[i]nability to correctly interpret dispersion staining colors.”⁹¹ The colors assigned to the particles are “simply wrong.”⁹² Dr. Su did not mince words:

I disagree with each and every single identification of “chrysotile” in Johnson’s Baby Powder made by Dr. Longo’s laboratory in the reports that I have reviewed. The data presented by MAS demonstrate systematic and chronic deficiencies in almost every aspect of operation, from the equipment setup and calibration to the sampling procedure, the sample preparation processes, the execution of the analytical procedure, and reporting quantification procedure, which leads me to conclude that the laboratory is incapable of performing the most basic aspects of PLM analytical procedure let alone correctly identifying chrysotile by PLM.⁹³

Mr. Lee Poye, an expert often on the *plaintiffs*’ side of cosmetic talc litigation similarly explains that the reason Dr. Longo is finding “chrysotile” in every talc bottle is because he is misidentifying talc as asbestos. Frequent plaintiffs’ expert Mr. Poye testified: “Q. In your opinion, what do those photos that Dr. Longo claims is chrysotile from that -- from his PLM analysis, what are those structures? A. The

⁹¹ (MDL Su Rep. at 12; *see also id.* at Ex. C at 6-9.)

⁹² (*Id.* at 4; *see also* Rep. of Ann G. Wylie, May 3, 2024, at 38 (“MAS misinterprets the dispersion staining colors of some elongate talc particles to produce values of the index of refraction parallel and perpendicular to elongation that are incorrect and inconsistent with the dispersion staining colors.”) (attached as Ex. 113 to Bush Decl.); Rebuttal Rep. of Matthew S. Sanchez, Ph.D., June 20, 2023, at 3 (attached as Ex. 114 to Bush Decl.).)

⁹³ (MDL Su Rep. at 12; *see also id.* at 33 (explaining why an analyst cannot evaluate merely the “edge” of a particle.)

edge of talc plates.”⁹⁴ Mr. Poye is the same person who, as discussed above, Dr. Longo sent samples to verify his results in the first round of reports in this MDL but found no asbestos. In fact, no one who has reviewed MAS’s imaging has been willing to go on record to agree that MAS is finding chrysotile by PLM.⁹⁵

Dr. Longo is calling yellow particles purple. His opinion is therefore not based on a reliable application of the methodology he claims to follow, and his PLM analysis should accordingly be excluded.

3. Dr. Longo’s PLM methodology should be excluded because his newest justification for calling yellow particles purple cannot be reproduced or independently verified.

Dr. Longo now has a new justification for why he is calling yellow particles purple. He claims that despite what everyone can see on the imaging he produced, one would need to look *live down the microscope* in order to understand and appreciate his analysis. But Plaintiffs and Dr. Longo opposed Defendants’ request to look at particles live at the same time as Dr. Longo. That renders Dr. Longo’s “chrysotile” opinion incapable of being tested or reproduced, further rendering his opinion inadmissible.

⁹⁴ (Dep. of Lee W. Poye 128:20-129:6, *McNeal v. Autozone, Inc.*, No. BC698965 (Cal. Super. Ct. Sept. 25, 2020) (“Poye *McNeal* Dep.”) (attached as Ex. 51 to Bush Decl.).)

⁹⁵ (Longo *MDL* (Vol. 1) Dep. 122:16-123:12.)

Under *Daubert* and Rule 702, a “key question” is whether the technique at issue “can be (and has been) tested.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993); see *In re Paoli R.R. Yard PCB Litig. (“Paoli II”)*, 35 F.3d 717, 742 (3d Cir. 1994) (discussing the “testability of the expert’s hypothesis”).

“Reproducibility is one of the hallmarks of reliable scientific testing and is pertinent to an analysis under *Daubert*.” *In re Zantac*, 644 F. Supp. 3d at 1130. “Someone else using the same data and methods must be able to replicate the result” of the expert. *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005). Thus “a key question” under *Daubert* and Rule 702 is “whether [a methodology] has been tested and independently validated or replicated.” *Ruffin v. Shaw Indus., Inc.*, 149 F.3d 294, 297 (4th Cir. 1998).

“Experts are now held to a level of accountability, that requires factual predicates, in historical fact, or in competent evidence, which allows a factfinder to independently verify the accuracy of the expert’s results. Absent such reliable verification, the expert’s opinion is not admissible.” *Kemp v. Tyson Seafood Grp., Inc.*, 2000 WL 1062105, at *7 (D. Minn. July 19, 2000); see also *United States v. Hebshie*, 754 F. Supp. 2d 89, 125 (D. Mass. 2010) (describing reproducibility as “the sine qua non of ‘science’”).

For example, an expert’s opinion was excluded where he “could not reproduce his own results when asked to re-score the slides using his own method.” *In re Diet*

Drugs, 2001 WL 454586, at *13 (E.D. Pa. Feb. 1, 2001); *see also United States v. Johnson*, 122 F. Supp. 3d 272, 330 (M.D.N.C. 2015) (excluding expert testimony because expert's subjective "methodology is seriously flawed and cannot be replicated"). Dr. Longo here similarly could not identify whether a particle was talc or asbestos when asked to look at the images he produced.

"[C]ourts across the country have excluded expert opinions based on scientific testing where the testing was inadequately documented to permit scrutiny and replication in the scientific community." *In re Zantac*, 644 F. Supp. 3d at 1130 (collecting cases). Indeed, as discussed above, this Court previously excluded Dr. Longo's PLM-amphibole because he did not produce his weight-percent standards. The Court explained: "Without that information, which is internally created by MAS, reproducing Dr. Longo's test under the PLM would not be possible, and hence, the testing is unreliable." *In re J&J*, 509 F. Supp. 3d at 155. Similarly, because Dr. Longo claims that looking down the microscope *live* is necessary to understand his analysis and that the imaging he produced is not sufficient, Defendants do not have the materials sufficient independently verify that justification.

Across multiple depositions and Rule 702-equivalent New Jersey state court hearing, Dr. Longo has repeatedly stated one would need to be physically sitting at a microscope looking live at the particle to understand how he was purporting to identify chrysotile:

- When asked to identify a particle in his report, Dr. Longo testified, “***I’d have to be looking in the microscope at it to tell you what that is***” and then said again: “***I’d have to be looking in the PLM scope to make a guess.***”⁹⁶
- When pressed on whether that particle was talc, he stuck to his same response: “***Again, I’d have to be looking in the microscope to make any decision on what that might be.***”⁹⁷
 - A video excerpt of these first two examples was previously lodged with the Court in connection with briefing on Defendants’ request for an inspection of Dr. Longo’s lab. *See* ECF No. 32227-15.
- When asked why he was identifying a so-called chrysotile particle as “magenta” when it was clearly not magenta, Dr. Longo stated as part of his answer that he would “***have to be under the microscope to look at it.***”⁹⁸
- When asked whether he was treating a different yellow “chrysotile” particle as purple for purposes of his analysis he said: “***I’d have to be sitting at the PLM scope.***”⁹⁹
- When asked if his lab was reporting yet another “chrysotile” particle as closer to the purple end of the light spectrum than a prior particle, Dr. Longo testified: “***I’m not looking in a microscope. I can’t answer it anymore and help you out here.***”¹⁰⁰
- When asked whether he could identify numerically (by the wavelength of light per the methodology Dr. Longo claims to follow) the color on specific area of the particle Dr. Longo claimed was relevant, he testified: “***No. In order for me to do that, I would have to be sitting at the microscope, in focus, out of focus, and look at that.***”¹⁰¹

⁹⁶ (Longo 3/3/23 *Valadez* Dep. 55:17-56:14.)

⁹⁷ (*Id.* 56:15-18.)

⁹⁸ (*Id.* 61:5-62:3.)

⁹⁹ (*Id.* 64:13-20.)

¹⁰⁰ (*Id.* 67:2-17.)

¹⁰¹ (*Id.* 78:13-79:9.)

- When asked what the refractive index of talc particles are, he again testified: *“I’d need to be looking in the microscope.”*¹⁰²
- *“I’d have to focus in on it* to see if we -- you know, the focus is off.”¹⁰³
- “[Y]ou have to be *looking under the microscope.*”¹⁰⁴
- “I’m *not sitting at the microscope* and this has been copied a few times, so it’s kind of hard to debate you on it.”¹⁰⁵
- *“I would need to be looking at the microscope here.”*¹⁰⁶
- “I don’t understand how he can make that decision in China when we’re over in the United States *never looking at the operative microscope.*”¹⁰⁷
- *“I’d have to be on the microscope.”*¹⁰⁸

Two of these examples of Dr. Longo’s “look-down-the microscope” testimony warrant closer examination. Identifying “asbestos” particles and differentiating them from talc particles is the entire point of Dr. Longo’s analysis. Yet when asked to identify a particle in his report as either talc or asbestos, Dr. Longo testified *three times* that he would need to be “looking in the microscope” to identify the particle.¹⁰⁹ Defendants lodged with the Court a video clip of this testimony in connection with

¹⁰² (*Id.* 39:17-40:14.)

¹⁰³ (Longo *Eagles* (Vol. II) Dep. 257:8-9.)

¹⁰⁴ (Longo *Clark Hr’g* (Vol. I.) Tr. 113:25-114:3.)

¹⁰⁵ (*Id.* 117:2-4.)

¹⁰⁶ (*Id.* 119:1-2.)

¹⁰⁷ (*Id.* 87:23-88:3.)

¹⁰⁸ (Longo *Clark Hr’g* (Vol. II) Tr. 290:2-8.)

¹⁰⁹ (Longo 3/3/23 *Valadez* Dep. 55:17-56:14.)

prior briefing showing Dr. Longo unable to identify the particle after looking at the images for a considerable amount of time.¹¹⁰

Similarly at the New Jersey Rule 702-like hearing at the end of May, Dr. Longo testified that the only way to determine whether his *entire analysis* is wrong is to be looking down the microscope:

[Q.] [I]f you're claiming to see some sort of edge effect here that you're basing your purple color on but it's an artifact, then ***your entire analysis is wrong?***

A. No, this analysis is not wrong. This is chrysotile ***and I would need to be looking at the microscope here.*** I stand by this. It's not wrong.¹¹¹

Dr. Longo's analyst Paul Hess who actually conducted the testing gave similar, but even more absurd testimony at his deposition. He agreed for example that one particle "is somehow entirely surrounded with purple, but we just can't see it" on the imaging Mr. Hess himself took because his conclusions were "[b]ased on what I saw through the microscope."¹¹² When asked, "can we verify that with the picture," Mr. Hess responded: "Other than what's on the picture, Counselor, I cannot speculate."¹¹³

Defense experts cannot look at the particles MAS called chrysotile live at the microscope because the slides with the samples MAS evaluated degrade in relatively

¹¹⁰ ECF No. 32227-15.

¹¹¹ (Longo *Clark Hr'g* (Vol. I) Tr. 118:20-119:3 (emphasis added).)

¹¹² (Hess *MDL Dep.* 115:15-25).

¹¹³ (*Id.* 117:8-11.)

short order and are then discarded by MAS.¹¹⁴ For example, Defendants requested Dr. Longo's slides in the *Valadez* case in California state court days after Dr. Longo issued his report in that case.¹¹⁵ But Defendants were later informed those slides were no longer usable at that time.¹¹⁶

As a result, Defendants requested to go to Dr. Longo's lab so that Dr. Longo and defense experts could look at the same particles at the same time live down the microscope as Dr. Longo claims is required.¹¹⁷ In fact, Dr. Longo even taunted Defendants to have a defense expert visit his lab: "I'd be perfectly happy to have, you know, Dr. Sanchez—well his PLM person come here—watch us make the sample. We can go and look for it and say here's the structure, go ahead and look at it. What's the difference? Probably better that way."¹¹⁸

But when Defendants tried to take Dr. Longo up on that offer, Plaintiffs opposed that motion and the Special Master did not permit that lab inspection. That

¹¹⁴ (Tr. 54:5-6, *Valadez v. Johnson & Johnson*, No. 22-CV-012759 (Cal. Super. Ct. March 15, 2023) ("3/15/23 *Valadez* CMC Tr.") (attached as Ex. 52 to Bush Decl.).)

¹¹⁵ (Letter from J. Romano to J. Satterley, March 9, 2023 ("3/9/23 Ltr.") (attached as Ex. 53 to Bush Decl.).)

¹¹⁶ (Tr. 55:15-21, *Valadez v. Johnson & Johnson*, No. 22-CV-012759 (Cal. Super. Ct. March 23, 2023) ("3/23/23 *Valadez* CMC Tr.") (attached as Ex. 54 to Bush Decl.).)

¹¹⁷ ECF 32227-1.

¹¹⁸ (Dep. of William E. Longo, Ph.D. 135:17-25, *Streck v. Johnson & Johnson*, No. 21-CI-06290 (KY Cir. Ct. May 16, 2023) ("Longo *Streck* Dep.") (attached as Ex. 55 to Bush Decl.).)

renders it impossible to verify Dr. Longo's "look-down-the-microscope" excuse (though Defendants have appealed the Special Master's decision to this Court). *See* ECF No. 32872-1. The Special Master expressly stated he was not determining how his ruling affected Rule 702 issues. ECF No. 32826 at 8-9.

In short: When Defendants point out the fatal flaws in Dr. Longo's approach, he now deflects all questioning into the fundamental issues with his methodology by claiming looking live down the microscope is necessary. That serves as the perfect excuse because it is impossible for the Defendants to test Dr. Longo's claim. And for those same reasons, his testimony should be excluded.

Because of the way Dr. Longo himself has defined his methodology as requiring live examination under his microscope, the Court, Defendants, and any future jury is left with the ipse dixit of Dr. Longo: *It is asbestos because I say so after I looked down the microscope. See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also Durkin v. Equifax Check Servs., Inc.*, 406 F.3d 410, 421 (7th Cir. 2005) (affirming exclusion of "untestable say-so"). That excuse is all the more nonsensical because Dr. Longo in fact rarely looked down the microscope himself. Rather, his analyst Paul Hess did. And as discussed below, that serves as another independent basis to exclude Dr. Longo's PLM testimony.

4. Dr. Longo's PLM methodology should be excluded because he is relying on another's judgment.

“An expert witness is permitted to use assistants in formulating his expert opinions, and normally they need not themselves testify.” *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612 (7th Cir. 2002). However, the “[a]nalysis becomes more complicated if the assistants aren't merely gofers or data gatherers but exercise professional judgment that is beyond the expert's ken.” *Id.* at 613. “The expert cannot vouch for the assistants' judgment where the soundness of that judgment is at issue.” *In re Zantac*, 644 F. Supp. 3d at 1136. “Absent an independent opinion based upon a reliable methodology, the expert is little more than a conduit or transmitter for hearsay.” *Hi-Tech Pharms. Inc. v. Dynamic Sports Nutrition, LLC*, 2021 WL 2185699, at *8 (N.D. Ga. May 28, 2021).

In the *Zantac* MDL, the court held that an expert's “heavy reliance on the judgment of analysts to develop, conduct, and document the ranitidine testing and then to interpret the results of that testing—judgment that the analysts exercised without guiding principles—is an additional factor weighing against the admissibility of [the expert's] opinions.” 644 F. Supp. 3d at 1138; see also *id.* at 1126 (expert's approach of “delegate[ing] the decisions about when and how to integrate to the judgment and discretion of individual analysts ... cannot withstand a *Daubert* challenge because it is not possible to assess the reliability of a methodology that simply leaves decisions to the expert”).

Here, Dr. Longo says that looking down the microscope is required to understand the basis for his findings. But he rarely did that: his analyst Paul Hess did. It is Paul Hess' judgment that is really at issue, but he is not the one who will testify to juries and be subject to cross examination at trial.

Dr. Longo has testified that in order to identify asbestos in talc by PLM, there “has to be an analyst doing the PLM that has experience in looking at these types of materials, so a lot of years” because doing the analysis properly “just depends on the experience and time and individual doing it.”¹¹⁹ In fact, he's said an analyst “would have to have decades of experience.”¹²⁰ In Dr. Longo's view, using a “a regular PLM setup with a PLM analyst that's not experienced in looking at this, he may never find it.”¹²¹

That's because the ability to accurately identify the color of a particle—a key PLM step—is a “judgment that comes from years and years of experience.”¹²² Dr.

¹¹⁹ (Dep. of William E. Longo, Ph.D. 125:11-13, 124:20-21, *Rimondi v. BASF Catalysts LLC*, No. MID-L-2912-17 (N.J. Super. Ct. Law Div. Jan. 7, 2019) (“Longo *Rimondi* 1/7/2019 Dep.”) (attached as Ex. 56 to Bush Decl.).)

¹²⁰ (Longo *Reyes* 09/25/2020 Dep. 129:12-13.)

¹²¹ (Dep. of William E. Longo, Ph.D. 374:16-18, *Zimmerman v. Autozone Inc.*, No. BC720153 (Cal. Super. Ct. May 12, 2020) (“Longo *Zimmerman* (Vol. II) Dep.”)) (attached as Ex. 57 to Bush Decl.).)

¹²² (Longo *Forrest* Dep. 73:11-13.)

Longo even believes that whether PLM analysis is “subjective depends on the analyst who’s performing the analysis.”¹²³

Dr. Longo is not a PLM analyst. In 2018, he testified: “I haven’t done PLM in such a long time.”¹²⁴ At least as of 2019, he had never “personally analyzed a [talco] sample for the presence of asbestos using PLM.”¹²⁵ As he put it then, “I don’t do PLM analysis.”¹²⁶ He has never taken a course on using PLM to detect asbestos¹²⁷ or on PLM dispersion staining in general.¹²⁸ He describes himself as “self-taught” in PLM.¹²⁹

The person who does Dr. Longo’s PLM work for him is his analyst Paul Hess, who has been conducting PLM analysis for almost 40 years, and has worked at MAS

¹²³ (Longo *Streck* Dep. 123:2-6; *see also id* at 123:14-15 (testifying that the level of subjectivity “just depends on your training and how much experience you’ve got.”).)

¹²⁴ (Dep. of William E. Longo, Ph.D. 61:2-3, *Allen v. Brenntag N. Am.*, No. DR180132 (Cal. Super. Ct. Sept. 14, 2018) (“Longo *Allen* (Vol. I) Dep.”) (attached as Ex. 58 to Bush Decl.).)

¹²⁵ (Longo *Young* Dep. 85:18-20.)

¹²⁶ (*Id.* 86:5-6.)

¹²⁷ (Longo 2/5/19 *MDL* Dep. 261:9-13.)

¹²⁸ (Dep. of William E. Longo, Ph.D. 278:8-10, *Lanzo v. Cyprus Amax Minerals, Co.*, No. MID-L-7385-16AS (N.J. Super. Ct. Oct. 30, 2023) (“Longo *Lanzo* (Vol. II) Dep.”) (attached as Ex. 59 to Bush Decl.).)

¹²⁹ (*Id.* 278:11-13.)

for 33 of them.¹³⁰ Testing talc for chrysotile by PLM has been “really up to one person” at MAS: Paul Hess.¹³¹ Every time MAS has reported finding “chrysotile” by PLM in Defendants’ talc products, Mr. Hess has been the analyst whose name appears on the analyst worksheets.¹³²

As the Special Master concluded, “Hess, not Longo, did the microscopic analysis required under the PLM methodology.”¹³³ Mr. Hess is “the one who’s looking through the PLM microscope to make the determination of the particle’s color.”¹³⁴ Mr. Hess is the one who makes “a determination to match it to a refractive index.”¹³⁵ Sometimes those values are reported in a range rather than a specific number because “Mr. Hess thinks it’s more accurate to do it that way.”¹³⁶ Mr. Hess

¹³⁰ (Dep. of William E. Longo, Ph.D. 53:3-8, *Krich v. Johnson & Johnson*, No. JCCP-4674/21STCV22952 (Cal. Super. Ct. Feb. 20, 2024) (“Longo *Krich* Dep.”) (attached as Ex. 60 to Bush Decl.).)

¹³¹ (Dep. of William E. Longo, Ph.D. 182:3-11, *Zundel v. Amerilure*, No. 22-2145 (Mass. Super. Ct. May 30, 2023) (“Longo *Zundel* Dep.”) (attached as Ex. 61 to Bush Decl.).)

¹³² (*See, e.g.*, Longo 2/28/23 Rep. at § 3 p.2.)

¹³³ ECF No. 32817.

¹³⁴ (Longo *Streck* Dep. 49:14-19.)

¹³⁵ (*Id.*)

¹³⁶ (*Id.* 108:23-109:3.)

is also the one who selects which images make it into the report.¹³⁷ In short, Mr. Hess is the one “identifying the particles” by PLM.¹³⁸

Dr. Longo has said that he will on infrequent occasions be called over to look at a particle, but that Mr. Hess is the one “person that [performs the analysis] from start to finish.”¹³⁹ Mr. Hess, not Dr. Longo is the one determining the particle’s color and matching it to its corresponding RI value—the critical steps in the analysis.¹⁴⁰ As part of that, he is the one choosing what *area* of the particle to use for the color match. And Dr. Longo cannot independently verify Mr. Hess’s conclusions because Dr. Longo says he needs to be at the microscope to preform that verification, which he did not do. And there is no longer any opportunity for Dr. Longo to make his own observations because the slides have long since degraded and been discarded.

Even worse, when Defendants sought a deposition of Mr. Hess, Plaintiffs opposed it. The Special Master granted the deposition. But unwilling to allow Mr. Hess to *actually* testify despite that ruling, the deposition was obstructed by *forty*

¹³⁷ (Dep. of William E. Longo, Ph.D. 134:24-135:1, *Alexander-Jones v. Avon Prods., Inc.* No. 22-2-18669-1-SEA (Wa. Super. Ct. Sept. 15, 2023) (“Longo *Alexander-Jones* Dep.”) (attached as Ex. 62 to Bush Decl.).)

¹³⁸ (*Id.* 135:3-8.)

¹³⁹ (Longo *Clark* Hr’g Vol. 1 Tr. 44:10-20; *see also* Longo *Young* Dep. 85:21-86:6 (Dr. Longo admits he “periodically will be asked by one of the analysts to take a look at this, what do you think”).)

¹⁴⁰ (Longo *Streck* Dep. 49:14-19.)

instructions not to answer questions.¹⁴¹ Here are just a *few* examples of the types of questions Mr. Hess was instructed not to answer. He was instructed not to answer: “In your reports identifying chrysotile in Johnson & Johnson, what color are the particles that you’re calling chrysotile typically?”¹⁴² He was instructed not to answer: “What color is the particle that you’re calling chrysotile here?”¹⁴³ He was instructed not to answer, “[What] color are you assigning the talc plates we’re looking at here?”¹⁴⁴

He was instructed not to answer: “[T]he same type of edge effects that you’re relying on to call particles chrysotile in Johnson & Johnson are also present on talc plates in your analysis; is that true?”¹⁴⁵ He was instructed not to answer whether the MAS’s initial use of the tungsten light bulb was “adding sort of darker golden colors or orange colors to the image.”¹⁴⁶

He was instructed not to answer whether he was treating a particular particle (that is in fact yellow) as “even more purple than standard reference chrysotile.”¹⁴⁷ He was instructed not to answer: “[W]hat you’re identifying as chrysotile in Johnson

¹⁴¹ (See generally Hess MDL Dep.)

¹⁴² (Id. 54:17-20.)

¹⁴³ (Id. 78:18-23).

¹⁴⁴ (Id. 124:5-24.)

¹⁴⁵ (Id. 143:11-25.)

¹⁴⁶ (Id. 95:1-9.)

¹⁴⁷ (Id. 110:19-112:14.)

& Johnson does not look like standard reference chrysotile, correct?”¹⁴⁸ When defense counsel attempted to direct Mr. Hess’s attention to a particular particle, he was even instructed not to answer the question: “Do you see that?”¹⁴⁹ Defendants have filed a motion to compel to require Mr. Hess to answer these questions, which is currently pending. *See* ECF No. 32993.

The Court should not indulge Plaintiffs’ and Dr. Longo’s attempt to shield his work from scrutiny by hiding behind his analyst, particularly when Defendants are not permitted to question that analyst on the most basic foundations of his opinion. *See Lawrence v. Raymond Corp.*, 2011 WL 3418324, at *7 (N.D. Ohio Aug. 4, 2001) (“An expert is not a black box into which data is fed at one end and from which an answer emerges at the other; the Court must be able to see the mechanisms in order to determine if they are reliable and helpful.”), *aff’d*, 501 F. App’x 515 (6th Cir. 2012).

Dr. Longo could not identify whether a particle was talc or chrysotile and claimed he needed to look down the microscope live. He defended himself from questioning that his “entire analysis” was wrong by saying he needed to look down the microscope live. But Dr. Longo is not the one looking live down the microscope. He is simply serving as a conduit for Mr. Hess, who is the one truly making all the

¹⁴⁸ (*Id.* 171:7-13.)

¹⁴⁹ (*Id.* 128:15-129:1.)

judgment calls. But Plaintiffs do not want and have prohibited Mr. Hess from answering even basic questions about the nature of the testing. All this is yet another reason Dr. Longo's PLM testimony should be excluded.

5. Dr. Longo's PLM methodology should be excluded because his birefringence calculations do not adhere to the methodology he claims to follow.

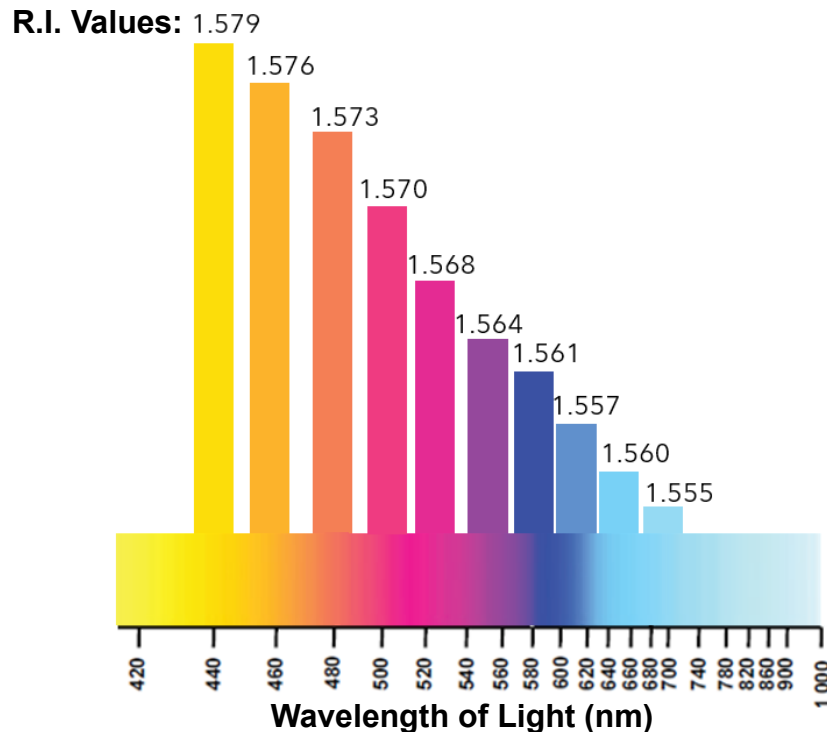
As discussed above, the colors the particle appears under the microscope is the starting point of the analysis. If MAS is not reliably reporting the colors, then Dr. Longo's PLM testing should be excluded for the reasons discussed above.

But those colors then serve as an input to another calculation called a "birefringence calculation" which helps determine the mineral type of the particle. Dr. Longo testified that he relies "very heavily on what is known as birefringence."¹⁵⁰

Chrysotile has a lower birefringence than talc. Even if Dr. Longo were accurately reporting the colors of the particles, his testing should be excluded for the additional reason, independent reason that he uses a flawed birefringence calculation. Specifically, he violates the methodology that he purports to follow to decrease the birefringence and therefore make the particles appear more like chrysotile.

¹⁵⁰ (Longo *Clark Hr'g* Vol. 1 50:9-15.)

Once the color of the particle is identified, it is matched to a wavelength of light (in nanometers) which in turn is matched to a chart that provides an associated “refractive index value” or “R.I.” Value.¹⁵¹ The more to the yellow end of the light spectrum, the higher the R.I. value:



The color a particle appears is different depending on whether the particle is oriented in “parallel” or “perpendicular” orientation. Particles in parallel will appear more towards the yellow side of the spectrum and therefore have higher R.I. values. Particles in perpendicular will appear more towards the blue side of the spectrum and therefore lower higher R.I. values.

¹⁵¹ (*Id.* 48:9-49:1, 113:12-18; *see also* R.I. Value Demonstrative.)

According to the ISO 22262-1 method Dr. Longo claims to follow, the formula for calculating birefringence is to take the **highest** R.I. value when in parallel orientation and subtracting the **lowest** RI value from perpendicular orientation:

$$\begin{array}{|c|} \hline \text{HIGHEST} \\ \text{Parallel RI} \\ \gamma \text{ (gamma)} \\ \hline \end{array} - \begin{array}{|c|} \hline \text{LOWEST} \\ \text{Perpendicular RI} \\ \alpha \text{ (alpha)} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Birefringence} \\ \hline \end{array}$$

In other words, the calculation requires using the “yellowist” color of the particle when in parallel and the “bluest” color when in perpendicular. ISO 22262-1 specifically defines “birefringence” as the “quantitative expression of the **maximum** difference in refractive index.”¹⁵²

Dr. Longo has admitted this means that under ISO you use the maximum difference when calculating birefringence.¹⁵³ Dr. Longo’s analyst Paul Hess who actually is the one who looks down the microscope and identifies the colors also testified that birefringence “is the difference between the mineral’s *highest* refractive indices and its *lowest* refractive indices” such that one finds the “maximum difference.”¹⁵⁴ Many other authorities state that the analyst should record highest-

¹⁵² ISO 22262-1 at 3 (emphasis added).

¹⁵³ (Longo *Prudencio* 7/7/2021 Tr. 5148:14-16) (“Q. So again, you’re talking about maximum difference in the ISO method; right? A. Yes.”.)

¹⁵⁴ (Hess *MDL* Dep. 50:11-51:18. (emphasis added).)

parallel/lowest-perpendicular refractive index and/or that birefringence represents the “maximum difference” between the refractive indices at each orientation.¹⁵⁵

Dr. Longo, however, has admitted that he does not perform his birefringence calculations in this way. Rather, he states that he uses the *average* R.I. value in parallel and compares that to the *average* R.I. value in perpendicular.¹⁵⁶ Moreover, he improperly derives these averages based on combining multiple particles that he believes “kind of represent” what he is seeing in the sample without any pre-defined protocol.¹⁵⁷

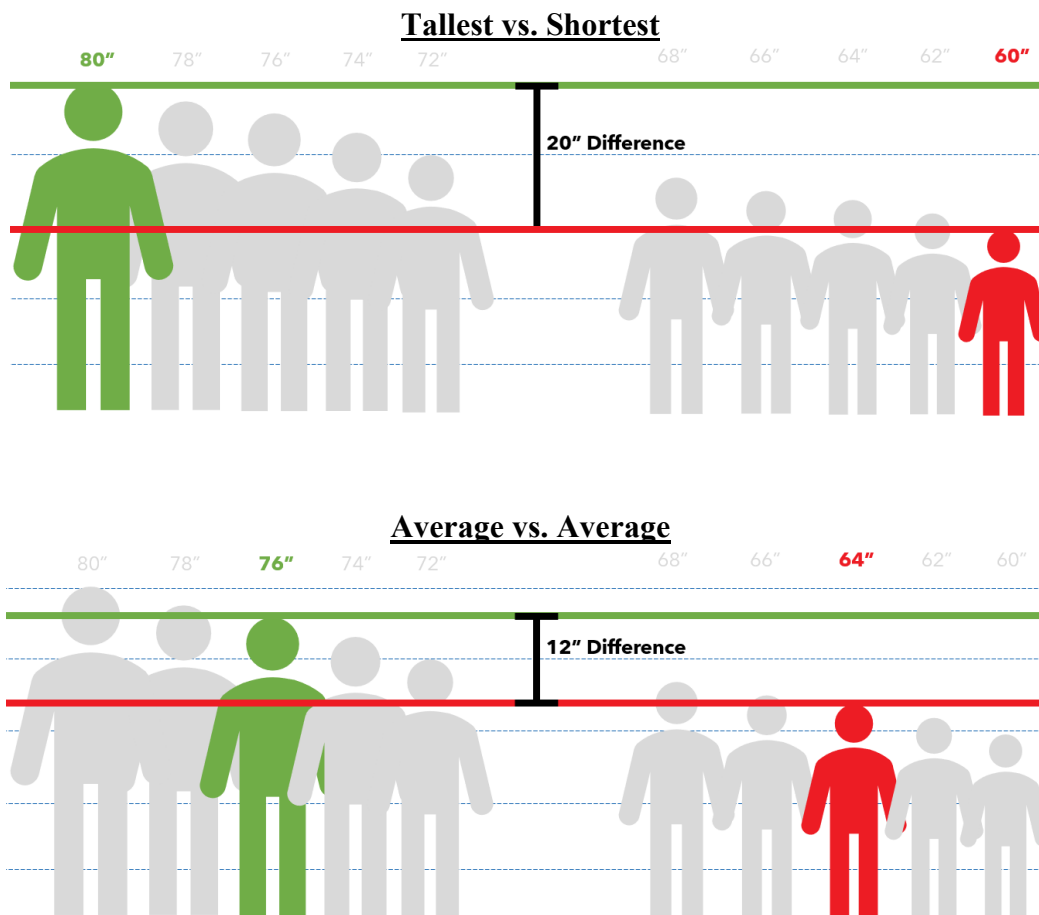
Using averages rather than “highest minus lowest” serves to arbitrarily decrease the birefringence value in violation of the ISO methodology he purports to follow. For example, imagine one wanted to compare the heights of the starting lineup of the Brooklyn Nets and a typical family of 5 people. If one were to compare the *tallest* Nets player to the *shortest* member of the family, that difference would

¹⁵⁵ (See, e.g., Scripa, AE, Linear Birefringence of Polymer Foils Determined by Optical Means (2017) at 67 (attached as Ex. 63 to Bush Decl.); Lee, J, et al. Optimal Treatment Condition for Changing Characteristics of Naturally Occurring Asbestos (2015) at 2335 (attached as Ex. 64 to Bush Decl.); Stoiber, R. E., & Morse, S. A. (1994). Crystal Identification and Optical Principles in Crystal Identification with the Polarizing Microscope. New York: Chapman & Hall, at 21 (attached as Ex. 65 to Bush Decl.).)

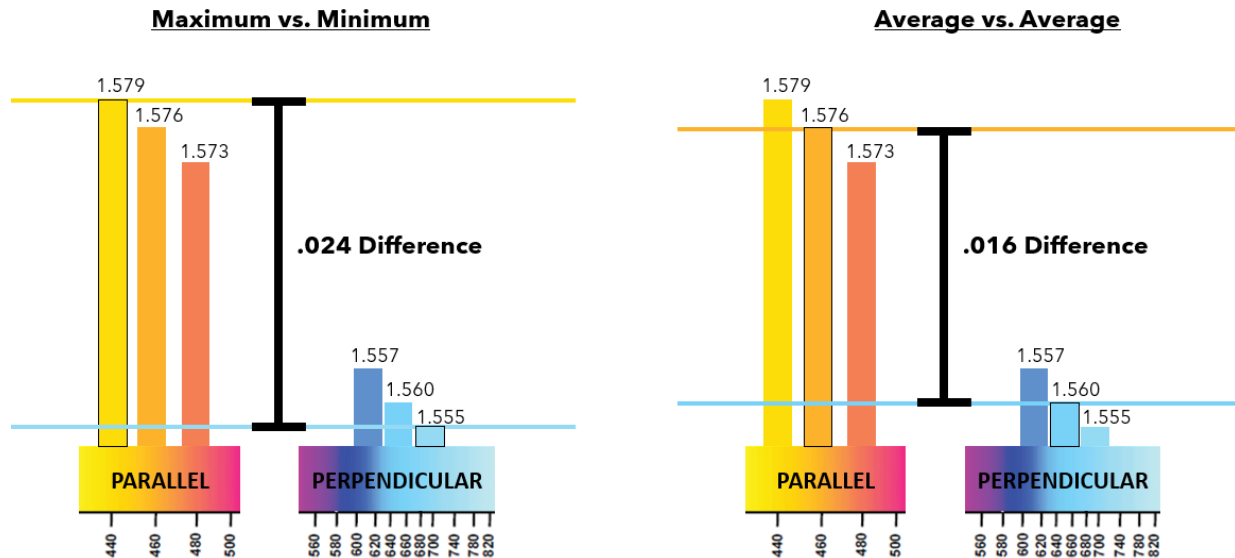
¹⁵⁶ (See Longo Prudencio 7/7/2021 Tr. 5144:4-22, 5147:3-24.)

¹⁵⁷ (See Longo Lanzo Dep. 265:20-25, 270:17-272:13.)

necessarily be greater than comparing the average-height Nets player to the average height family member:



Similarly, by calculating the difference between *average* R.I. values rather than the difference between the *highest* R.I. value and the *lowest*, Dr. Longo is decreasing the birefringence value. It not only violates his own method, but it makes the particle appear more like asbestos because chrysotile asbestos has lower birefringence than talc.



Dr. Longo's PLM testing should be excluded for the additional independent reason that he is not reliably performing a birefringence calculation in violation of his own method.

II. This Court Should Exclude Dr. Longo's Amphibole-TEM Opinions.

This Court should not stop at excluding Dr. Longo's PLM testing for chrysotile asbestos. It should also exclude Dr. Longo's TEM testing for amphibole asbestos.

A. Background on asbestos and TEM testing

1. What is Asbestos?

"Asbestos" is a collective term describing a group of six minerals that, under certain rare geological conditions, can form in bundles composed of long, thin,

extremely flexible fibers.¹⁵⁸ When they form in this unique way, they are “asbestiform.”¹⁵⁹ When they do not, they are “nonasbestiform.”¹⁶⁰

The way a mineral forms in nature is known as its “habit.”¹⁶¹ Thus, “asbestiform” is an adjective that describes the distinctive growth pattern – or habit – of asbestos minerals.¹⁶² Minerals that crystallize in an asbestiform habit have a crystal structure that can be separated into fibers with high tensile strength and flexibility.¹⁶³

Each of the six minerals comes in a nonasbestiform, and (much more rarely) an asbestiform version:¹⁶⁴

¹⁵⁸ E.g., EPA R-93; Int’l Org. for Standardization, *Ambient Air – Determination of asbestos fibres – Direct-transfer transmission electron microscopy method 2* (1995); IARC 2010 Monograph; NIOSH Roadmap.

¹⁵⁹ IARC 2010 Monograph at 277; ISO 22262-1.

¹⁶⁰ IARC 2010 Monograph at 277.

¹⁶¹ ISO 22262-1 at 5.

¹⁶² IARC 2010 Monograph at 277.

¹⁶³ ISO 22262-1 at 2; IARC 2010 Monograph at 277; EPA R-93 at A-1; NIOSH Roadmap at 7, 9.

¹⁶⁴ Int’l Agency for Research on Cancer, World Health Org., 100 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dusts* 220 (2012) (“IARC 2012 Monograph”) (attached as Ex. 66 to Bush Decl.); see also IARC 2010 Monograph at 277, 411-13 (“[T]hese six minerals occur more commonly in a nonasbestiform habit.”). Five of these minerals belong to the amphibole mineral family; chrysotile, by contrast, belongs to the serpentine mineral family. While both groups are sheet silicates, they have distinct chemical formulas. See ISO 22262-1 at 2, 7. For example, amphiboles generally contain iron; serpentine minerals do not. *Id.*

Mineral Family	Non-Asbestiform	Asbestiform
Serpentine	Antigorite/Lizardite	Chrysotile
Amphibole	Riebeckite	Crocidolite
Amphibole	Grunerite-Cummingtonite	Amosite
Amphibole	Tremolite	Tremolite Asbestos
Amphibole	Anthophyllite	Anthophyllite Asbestos
Amphibole	Actinolite	Actinolite Asbestos

The World Health Organization’s International Agency for Research on Cancer (“IARC”) – one of the authorities plaintiffs’ medical experts primarily rely on for their causation opinions – explained: “[W]hen asbestiform, they constitute asbestos and, when not asbestiform, they are referred to as mineral fragments or cleavage fragments.”¹⁶⁵

As the above chart demonstrates, asbestiform and nonasbestiform varieties of the same mineral sometimes have similar names, and sometimes entirely different names. For example, “riebeckite is the non-asbestos version of crocidolite.”¹⁶⁶ By contrast, there “are asbestos types of tremolite, there are non-asbestos types of tremolite.”¹⁶⁷ Accordingly, as Dr. Longo acknowledges, the “word tremolite does not automatically mean asbestos.”¹⁶⁸ The two are typically distinguished by referring to the nonasbestiform variety as simply “tremolite,”

¹⁶⁵ IARC 2010 Monograph at 277. (See also Dep. of Robert Cook, Ph.D. 108:14-20, Jan. 30, 2019 (attached as Ex. 67 to Bush Decl.) (it is the “asbestiform version of those amphiboles that is defined as, quote, asbestos”).)

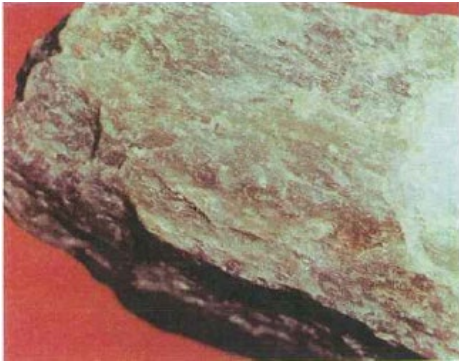
¹⁶⁶ (Longo *Rimondi* Tr. Vol. I 141:23-25.)

¹⁶⁷ (*Id.* 142:24-143:1; Rigler *MDL* Dep. 201:2-4.)

¹⁶⁸ (Longo *Rimondi* Tr. Vol. I. 142:11-13.)

while referring to the asbestiform variety as “asbestiform tremolite” or “tremolite asbestos.”

Because they formed differently in nature, asbestiform and nonasbestiform minerals have different properties. For example, asbestiform minerals “possess high tensile strength and flexibility.”¹⁶⁹ And though they have the same chemical composition, the two look very different because of the different geological conditions in which they were formed:¹⁷⁰



Nonasbestiform Tremolite



Asbestiform Tremolite

Every federal regulation or statute defines asbestos in a similar way. For example, the regulations promulgated by OSHA define “asbestos” as only the asbestiform varieties of the six regulated minerals. 29 C.F.R. § 1910.1001(b). The federal regulations promulgated by the Environmental Protection Agency (“EPA”) similarly define “asbestos” as “the *asbestiform varieties*” of those minerals. 40

¹⁶⁹ (Longo 2/1/2019 MDL Rep.)

¹⁷⁰ Campbell et al., Bureau of Mines, *Selected Silicate Minerals and Their Asbestiform Varieties* 7 (1977) (“Campbell 1977”) (attached as Ex. 68 to Bush Decl.).

C.F.R. § 763.163; 40 C.F.R. § 61.141 (same); *see also* 16 C.F.R. § 1304.3(b) (Consumer Product Safety Commission regulation) *See also Hanson v. Colgate-Palmolive Co.*, 353 F. Supp. 3d 1273, 1278 (S.D. Ga. 2018) (relying on the OSHA and EPA definition). The U.S. Mine Safety and Health Administration (“MSHA”), which regulates talc mines and mills, defines asbestos in the same way, 30 C.F.R. § 56.5001(b), and has expressly stated that its definition of asbestos “does not include nonfibrous or nonasbestiform minerals,” *see* 73 Fed. Reg. 11284, 11292 (2008); *see also* 39 Fed. Reg. 24317 (“Tremolite of a nonasbestiform which occurs in talc deposits is not mentioned in the definition [of asbestos] and, therefore, is not covered.”).

Congress, too, has embraced this fundamental distinction between asbestos and nonasbestiform minerals. For example, the Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.*, authorizes federal regulation of toxic substances that pose health hazards. It limits the definition of asbestos to “asbestiform varieties” of the six minerals. 15 U.S.C. § 2642(3).

Accordingly, in order to determine whether particles are asbestos, one must conclude that (1) they are one of the six relevant minerals, and (2) they are the asbestiform version of that mineral. As one of the protocols Drs. Longo and Rigler purport to rely on explains: “Since the non-asbestiform analogues of the

amphiboles are not generally regulated, it is also *necessary to discriminate between the asbestiform and nonasbestiform analogues* of these minerals.”¹⁷¹

2. Cleavage fragments are not asbestos.

MSHA explains that “when pressure is applied, the nonasbestiform crystals fracture into prismatic particles, which are called cleavage fragments because they result from the particle’s breaking or cleavage. Cleavage fragments may be formed when nonfibrous minerals are crushed, as may occur in mining and milling operations.” 73 Fed. Reg. 11284 (2008).

Nonasbestiform amphibole is like ordinary rock, no matter what one does with it. As Dr. Longo explained, “You can’t take pieces of the non-asbestos rock and break it up and then call it asbestos.”¹⁷² Regardless of size, nonasbestiform particles simply have not crystallized in the specific way that leads to the unique properties that make them asbestos, and that make asbestos dangerous.

Based on over 25 years of study, the medical and regulatory communities have embraced the distinction between asbestiform and nonasbestiform minerals. In 1992, OSHA undertook a comprehensive study of scientific data and opinions to determine whether nonasbestiform minerals should be regulated as asbestos.¹⁷³ The

¹⁷¹ Int’l Org. for Standardization, *Air Quality – Bulk Materials: Part 2: Quantitative determination of asbestos by gravimetric and microscopical methods* 13 (2014) (“ISO 22262-2”) (attached as Ex. 69 to Bush Decl.) (emphasis added).

¹⁷² (Longo *Rimondi* Tr. Vol. I. 147:23-148:1.)

¹⁷³ 57 Fed. Reg. 24310 (1992).

agency reviewed decades of testing and literature and determined that “substantial evidence is lacking to conclude that non-asbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos.”¹⁷⁴ Specifically, the agency found no credible link between exposure to nonasbestiform minerals and cancer.¹⁷⁵

The United States Geological Survey (“USGS”) states that “when it comes to health risk,” it “matter[s] whether an amphibole is asbestiform,” and that “available evidence supports a conclusion that exposure to nonasbestiform cleavage fragments is not likely to produce a significant risk of developing asbestos-related disease.”¹⁷⁶ NIOSH – OSHA’s scientific and research arm – has similarly declared that “nonasbestiform minerals are not ‘asbestos’ or ‘asbestos minerals,’” and only “exposure to fibers from the asbestos minerals” is credibly linked to adverse health effects in epidemiological studies.¹⁷⁷

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 24311.

¹⁷⁶ U.S. Geological Survey, *Some Facts About Asbestos 2* (2001) (attached as Ex. 70 to Bush Decl.) (quoting 57 Fed. Reg. 24310).

¹⁷⁷ NIOSH Roadmap at vii, 3; *see also Lanzo v. Cyprus Amax Mins. Co.*, 467 N.J. Super. 476, 503 (App. Div. 2021) (vacating a trial verdict due to testimony that “non-asbestiform minerals can cause mesothelioma” which should not have been admitted under the state equivalent of Rule 702); Letter from A. G. Ulsamer, Ph.D., Assoc. Exec. Dir., U.S. Consumer Prod. Safety Comm., to Thomas J. Germine, Esq., Feb. 8, 1988, at 4 (“In some instances, there may be playsand on the market that contains particles of the non-asbestos form of tremolite that meet

Also, perhaps most importantly for these proceedings, none of plaintiffs' *medical* experts has presented any evidence that cleavage fragments cause ovarian cancer. When asked whether he factored into his opinions "the difference between asbestiform and non-asbestiform minerals," plaintiffs' gynecological oncologist Dr. Clarke-Pearson only stated "[w]ell, I'm quite certain, based on IARC, that asbestiform minerals are carcinogenic."¹⁷⁸ Despite the questioner prompting him to do so, he did not state whether in his opinion nonasbestiform minerals were carcinogenic as well.¹⁷⁹ In fact, neither Dr. Clarke-Pearson nor Dr. Singh, one of plaintiffs' epidemiologists, even knew what cleavage fragments were when asked at their depositions.¹⁸⁰ It is for these reasons that plaintiffs' experts need to stretch their made-for-litigation definition of asbestos.

the OSHA definition of 'fiber.' We do not believe that the available data are sufficient to establish that a carcinogenic or other hazard is associated with exposure to the non-asbestos form of tremolite particles." (attached as Ex. 115 to Bush Decl.).

¹⁷⁸ (Dep. of Daniel L. Clarke-Pearson, M.D. 287:7-17, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. Feb. 4, 2019) (attached as Ex. 71 to Bush Decl.).)

¹⁷⁹ (*See id.* 287:19-20.)

¹⁸⁰ (*See id.* 286:10-12; Dep. of Sonal Singh, M.D., M.P.H. 298:9-12, *In Re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs., and Prods. Liability Litig.*, MDL No. 16-2738 (D.N.J. Jan. 16, 2019) (attached as Ex. 72 to Bush Decl.).)

3. Dr. Longo and Dr. Rigler's TEM methodology.

Despite the presence of clear definitions for “asbestos” and “asbestiform” in the methodologies and regulations they rely on, Dr. Longo and Dr. Rigler simply ignore them. Instead, they define what they call “asbestos” solely by reference to whether a mineral structure meets certain “counting criteria.” For example, Dr. Longo agrees that if you break up a non-asbestos rock of tremolite it does not magically, in fact, become asbestos.¹⁸¹ However, because of the way amphibole rocks break, you can get some pieces that would be longer and thinner and could resemble asbestos fibers if examined individually.¹⁸² Even though he agrees that that is *not* asbestos, Dr. Longo and Dr. Rigler would use their “counting criteria” to call it asbestos.¹⁸³

4. The prior Rule 702 opinion

This Court previously denied Defendants' motion on Dr. Longo and Dr. Rigler's TEM amphibole testing. The Court concluded that “[p]erceived weaknesses in Dr. Longo's methods, such as those identified here by Defendants, go to weight rather than to admissibility.” *In re J&J*, 509 F. Supp. 3d at 149; *see also id.* at 151 (“The Court again finds that these issues go to the weight of Dr. Longo's opinions,

¹⁸¹ (Longo *Rimondi* Tr. Vol. I 149:11-17.)

¹⁸² (*Id.* 148:8-10.)

¹⁸³ (*Id.* 149:18-20.)

rather than reliability.”); *id.* at 152 (“[A]ny purported inaccuracies in his method of counting go more appropriately to the weight of his opinion rather than reliability.”).

The Court also stated that its role was “simply to evaluate whether the *methodology* used by the expert is reliable, i.e., whether, when correctly employed, that methodology leads to testimony helpful to the trier of fact.” *Id.* at 150 (emphasis in original) (quoting *Walker v. Gordon*, 46 F. App’x 691, 695-96 (3d Cir. 2002)).

But Rule 702 was amended to ensure courts would not conduct exactly that sort of analysis. Whether the methodology *in the abstract* is reliable is not the only inquiry. Testimony must also be excluded if “the expert’s *opinion* reflects a *reliable application* of the principles and methods” that the expert claims to employ. Rule 702(d). This amendment was intended to “emphasize that the court must focus on the expert’s opinion and must find that the opinion actually proceeds from a reliable application of the methodology.” Committee Committee on Rules of Practice & Procedure, Agenda Book, Tab 7A, “Report to the Standing Committee,” at 871 (June 7, 2022).

The Committee Notes similarly state that “many courts ha[d] held that the critical questions of the sufficiency of an expert’s basis, and the application of the expert’s methodology, are questions of weight and not admissibility” which were an “an incorrect application of Rules 702 and 104(a).” 2023 Committee Notes, Rule

702. The prior Rule 702 decision in this MDL therefore rests on a basis that is no longer viable under the amendments to Rule 702.

B. Dr. Longo and Dr. Rigler do not reliably distinguish between asbestos and non-asbestos cleavage fragments.

1. Dr. Longo and Dr. Rigler will count particles as asbestos even when they're not.

Dr. Longo acknowledges that the “structure [that] comes from breaking apart non-asbestos” minerals does “not magically become, in fact, asbestos.”¹⁸⁴ But his lab will nevertheless “count it and report it in [his] reports as asbestos.”¹⁸⁵

Put another way, Dr. Longo has agreed that if one of his “analysts who is conducting the test sees a non-asbestiform amphibole cleavage fragment,” of a certain size and shape, “the analyst will count that as an asbestos structure.”¹⁸⁶ Seeing a non-asbestos cleavage fragment but calling it “asbestos” anyway is not a valid methodology or a reliable application of one.¹⁸⁷

¹⁸⁴ (Longo *Rimondi* Tr. Vol. I 149:14-17.)

¹⁸⁵ (*Id.* 149:18-20.)

¹⁸⁶ (Longo *Olson* Tr. 1717:3-9.)

¹⁸⁷ Dr. Longo has *said* (under oath) that he has tested cosmetic talc only for purposes of litigation, and only began doing so in 2017 after being contacted by plaintiffs’ attorneys. (Longo *Leavitt* Tr. 170:16-171:11.) But back in 2002 before he was hired for this litigation he testified: “[W]e have done our own studies on talc, but what I haven’t been able to do is find a cosmetic where I can say, yes, that has asbestos in it.” (Longo 7/18/02 *Starkweather* Dep. 155:20-23.) He said then that he was “very familiar” with the issue and that cosmetic talc containing asbestos was “an urban legend.” (*Id.* at 155:10-17; *see also* Longo 5/28/02 *Manbodh* Dep. 106:11-19 (“We’ve looked. We have not found it.”).)

Drs. Longo and Rigler treat as asbestos every amphibole particle that has an aspect ratio greater or equal to 5:1, a length greater or equal to .5 microns, and parallel sides.¹⁸⁸ (Note that this definition sweeps in minerals that *cannot* be asbestos because they are not asbestiform, which Dr. Longo concedes.¹⁸⁹) Drs. Longo and Rigler reach this puzzling result by deliberately confusing the definition of asbestos and “counting criteria.”

Certain standards govern how analysts should count asbestos fibers after they have been identified; Drs. Longo and Rigler refer to these as “standard . . . counting rules,” citing for support, among other things, the Asbestos Hazard Emergency Response Act (“AHERA”) regulations.¹⁹⁰ But Drs. Longo and Rigler ignore the text of that representative rule, as well as the context in which it was developed, in the way that they use it.¹⁹¹ This methodological failing renders their purported identification of asbestos wholly unreliable.

¹⁸⁸ (See Longo 2/1/2019 *MDL* Rep. at 12 (“Amphibole fibers or bundles with substantially parallel sides and an aspect ratio of 5:1 or greater, and at least 0.5 [micrometers] in length were counted as regulated asbestos”); *id.* at 13 (“All amphibole fibers/bundles that meet the above-stated size criteria were recorded on . . . structure count bench sheets for each sample.”).)

¹⁸⁹ (See Longo 2/5/19 *MDL* Dep. 72:1-18.)

¹⁹⁰ (See Longo 2/1/2019 *MDL* Rep. at 12.)

¹⁹¹ According to Dr. Longo, all of the standards he invokes “have the same counting rules.” (Longo 2/5/19 *MDL* Dep. 220:15-16.)

The AHERA counting rules are found in Appendix A to 40 C.F.R. § 763. Those regulations define a *fiber* as “[a] structure greater than or equal to 0.5 [micrometers] in length with an aspect ratio (length to width) of 5:1 or greater and having substantially parallel sides.” 40 C.F.R. § 763 app. A § II.A.9; *see also id.* § II.F.9.a.i. By citing this language in their Report, Drs. Longo and Rigler act as though this is AHERA’s definition of *asbestos*. It is not. These very same AHERA regulations define asbestos consistent with its universally accepted definition: the *asbestiform* varieties of the six regulated minerals. 40 C.F.R. § 763.83.

Thus, the fact that a particle meets this definition under the counting criteria means simply that it is a fiber; it doesn’t provide any information about what kind of fiber it is. Thus, a different portion of the AHERA counting rules—one Drs. Longo and Rigler ignore—addresses the issue of identifying the fiber. What AHERA states “shall be recorded on the count sheet” is an “*asbestos* fiber.” 40 C.F.R. § 763 app. A § II.F.9.a (emphasis added). And, again, AHERA defines asbestos as the *asbestiform* varieties of the six regulated minerals. 40 C.F.R. § 763.83. Yet Dr. Longo and Dr. Rigler will count all “fibers” of the minerals as “asbestos” even if not *asbestiform* and therefore not asbestos.

It is also critical to consider the context in which these rules are applied. AHERA relates to remediation, i.e., the process of removing asbestos from schools and other environments where asbestos is known to be present. *See, e.g.*, 15 U.S.C.

§ 2641(b). In that situation – for example, removing asbestos-containing insulation from a school – *there is no dispute that the material being removed is asbestos as opposed to a nonasbestiform cleavage fragment*. When the presence of asbestos is known and the only question is how much, there is no need to first confirm the presence of asbestos. In this context, it is unsurprising that the counting rules do not include a separate, explicit step directing the analyst to distinguish asbestiform fibers from nonasbestiform cleavage fragments.¹⁹²

But the fact that this step does not appear in the counting rules (which are applicable when one has already determined that asbestos is present) does not mean that no such step is required where, as here, the presence of asbestos is disputed. Indeed, AHERA *does* require such a step; it just is not listed in the counting rules and is instead part of the process for identifying asbestos *before* the counting rules are implicated. *See, e.g.*, 40 C.F.R. § 763.87(b) (citing Appendix E).

¹⁹² To the extent AHERA sets out a precautionary strategy to ensure maximum protection of human health, that regulatory decision is not a substitute for the rigorous analysis required of expert testimony. *See, e.g., In re Zicam Cold Remedy Mktg., Sales Practices & Prods. Liab. Litig.*, No. 09-md-2096-PHX-FJM, 2011 WL 798898, at *10 (D. Ariz. Feb. 24, 2011) (agency’s “prevention-oriented” standards are “materially different” from *Daubert*); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) (agencies employ a risk-utility analysis distinct from the scientific standard demanded by a court); *cf. Hanson*, 353 F. Supp. 3d at 1281 (steps that do not distinguish asbestiform from nonasbestiform particles are “sufficient for regulatory action but not anticipated litigation”).

Imagine the various criteria one might have for counting poisonous mushrooms. For a field already known to be full of only poisonous mushrooms, the counting criteria could be “fungus with a large cap, and a stem.” But the same criteria would be useless where the presence of poisonous mushrooms could not be assumed. In that situation, one would need to add a criterion to test for toxicity. In neither case is the definition of “poisonous mushroom” different, even though the *counting criteria* are vastly different.

Drs. Longo and Rigler’s attempt to import the counting rules into this context fails the Rule 702 test; it is an unreliable method because it is simply not designed to answer the question at issue. A central consideration under Rule 702 and *Daubert* is “fit,” consisting of “the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.” *Paoli II*, 35 F.3d at 742-43 (internal citation and quotation marks omitted). An “expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact,” *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003) (internal citation and quotation marks omitted), keeping in mind that “scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes,” *Daubert*, 509 U.S. at 591.

Under this framework, it would clearly be impermissible for Drs. Longo and Rigler to import a methodology developed for identifying the amount of asbestos

known to be present to a context where the entire point of the analysis is to determine whether or not asbestos is present in the first instance; it fails to answer the relevant question and is thus inherently unreliable. *See, e.g., Schepise v. Saturn Corp.*, No. CIV.A. 94-385(MLP), 1997 WL 897676, at *17 (D.N.J. July 30, 1997) (criticizing reliance on studies conducted “in entirely different settings” from that at issue); *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 667-68 (D.N.J. 2008) (expert’s (mis)use of statements by the CDC and FDA lacked requisite fit due to different assumptions and factual contexts underlying those statements from the litigation at hand); *Habecker v. Clark Equip. Co.*, 36 F.3d 278, 290 (3d Cir. 1994) (accident reconstruction properly excluded where it failed to replicate conditions and thus did “not ‘fit’ the facts of th[e] case”).

But what Drs. Longo and Rigler did is even worse than simply trying to import inapposite rules. They misrepresent what the counting rules do and given how much more common nonasbestiform amphiboles are than asbestiform amphiboles, *see supra* at III.C.1, the failure to distinguish the two leads to particularly misleading results.

The original Rule 702 ruling stated that it was “fatal” to Defendants’ argument that Defendants supposedly did “not identify different ‘counting rules’ that should be used, or point to any other specific rules used by the scientific

community under these circumstances.” *In re J&J*, 509 F. Supp. 3d at 149. The Plaintiffs never even made this argument in their opposition brief.

Putting aside the fact that alternative methodologies are irrelevant if the methodology the *expert used* is not reliable or was applied in an unreliable way, alternate methods *do* in fact exist. A method called EPA R-93—attached as exhibit 21 to the Defendants’ original motion—specifically outlines ways to differentiate asbestiform from nonasbestiform minerals based on particular characteristics.¹⁹³ Additionally, U.S. Pharmacopeia method 901 uses similar criteria and was specifically designed for testing pharmaceutical grade talc.¹⁹⁴

In other words, unlike the AHERA counting criteria Dr. Longo relies on that only come into play once asbestos is known to be present, EPA R-93 and USP 901 are specifically designed to differentiate asbestiform and nonasbestiform minerals. This prior decision’s reasoning on a lack of alternative methods can no longer stand.¹⁹⁵

¹⁹³ EPA R-93 at A-1.

¹⁹⁴ U.S. Pharmacopeia method 901, Detection of Asbestos in Pharmaceutical Talc (attached as Ex. 73 to Bush Decl.).

¹⁹⁵ The original order also stated that Dr. Longo testified that “TEM eliminate most of [the non-asbestiform cleavage] fragments based on their chemistry and electron diffraction pattern.” *In re J&J*, 509 F. Supp. 3d at 150. That is not the issue. The chemistry and electron diffraction pattern can be used to determine whether the mineral is tremolite. But what is at issue in this motion are tremolite particles that are not asbestiform and not asbestos for that reason. Chemistry and electron diffraction patterns say nothing about.

2. Dr. Longo and Dr. Rigler’s “bundles” excuse is not reliable.

Dr. Longo has in fact long acknowledged that visual TEM analysis cannot determine whether a single “fiber” is asbestiform or nonasbestiform.¹⁹⁶ This concession is unsurprising; the testing methods that Dr. Longo uses (like ISO 13794, for determining asbestos in air) explicitly state that the method cannot distinguish between individual fibers of asbestos and nonasbestiform particles.¹⁹⁷ Drs. Longo and Rigler therefore turn to claiming that they are finding “bundles” which they say are by definition asbestos. This “bundle” excuse suffers from several fatal methodological flaws.¹⁹⁸

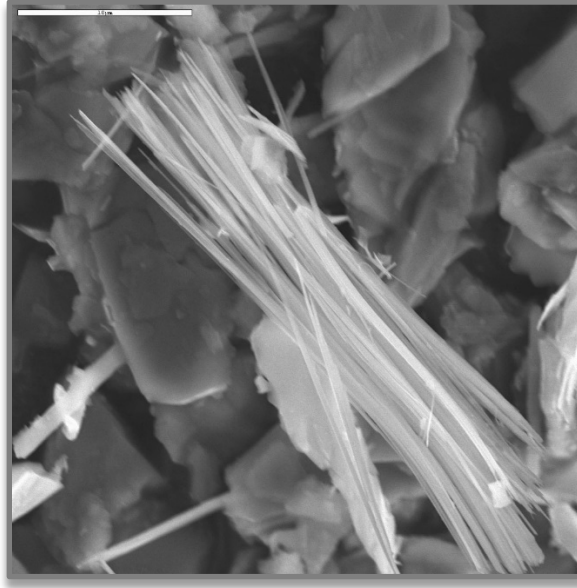
First, the problem with Drs. Longo and Rigler’s methodology for identifying “bundles” is simple: There is no methodology. In fact, they fail to employ generally accepted visual cues for what constitutes a bundle of asbestos fibers. Bundles occur

¹⁹⁶ (See, e.g., Dep. of William E. Longo, Ph.D. 45:10-13, *Anderson v. Borg-Warner Corp.*, No. JCCP 5674/BC666513 (Cal. Super. Ct. Mar. 29, 2018) (“Longo 3/29/18 *Anderson* Dep.”) (attached as Ex. 74 to Bush Decl.) (“[T]here’s no way to tell with just TEM, if you’re looking at a single fiber, if it’s asbestiform or not.”); Longo *Herford* Dep. Vol. I 111:12-20 (same); Longo *Rimondi* Tr. Vol. I 164:18-21, 172:18-22 (same).)

¹⁹⁷ (E.g., Longo 2/5/19 *MDL* Dep. 221:14-222:19.)

¹⁹⁸ The original Rule 702 order concluded that “whether a particular asbestiform is a fiber or bundle does not make any qualitative difference since they are both asbestos.” *In re J&J*, 509 F. Supp. 3d at 151. But that puts the cart before the horse. The way Dr. Longo is claiming the particles are asbestiform is *because* they are bundles. And he acknowledges his methods do not allow him so determine whether a single fiber is asbestiform or not.

as separable groups of parallel fibers with splayed ends and matted masses as seen here:¹⁹⁹



This is consistent with the same ISO standard on which Dr. Longo relies, which similarly indicates that “fibre bundles displaying splayed ends” are more likely to be *asbestiform*.²⁰⁰

Longo and Rigler have been unable to articulate any objective criteria to be used in their visual analysis.²⁰¹ For example, when asked how he could tell that the

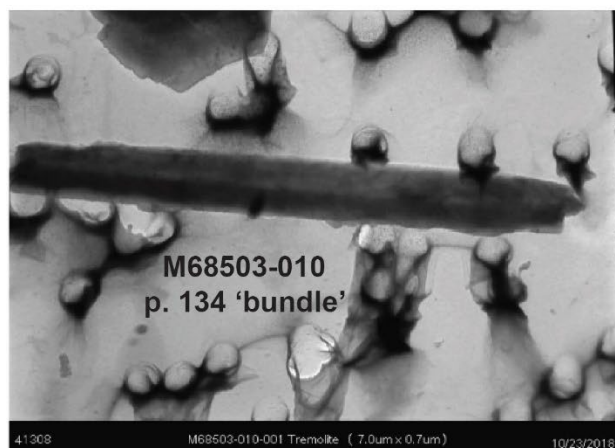
¹⁹⁹ Van Gosen et al., *A USGS Study of Talc Deposits and Assoc. Amphibole Asbestos Within Mined Deposits of the Southern Death Valley Region, Cal.*, U.S. Geological Survey Open-File Rep. 2004-1092, U.S. Dep’t of Interior at 7 (attached as Ex. 116 to Bush Decl.).

²⁰⁰ ISO 22262-1 at 22.

²⁰¹ Dr. Longo claims to have “internal MAS-generated reference samples for TEM to identify asbestos.” (Longo 2/5/19 *MDL* Dep. 42:9-12.) If these exist, the PSC decided not to produce them. (*See id.* 42:16-17.) And in any event, they fail to produce reliable results.

image he was looking at was a bundle of fibers as opposed to a single fiber, he answered simply: “Because I can see them.”²⁰² And Dr. Longo has repeatedly acknowledged that the inquiry is subjective, indicating that “the analyst is ultimately making the decision if it is a single fiber or a bundle.”²⁰³ In other words, whatever Dr. Longo says goes.

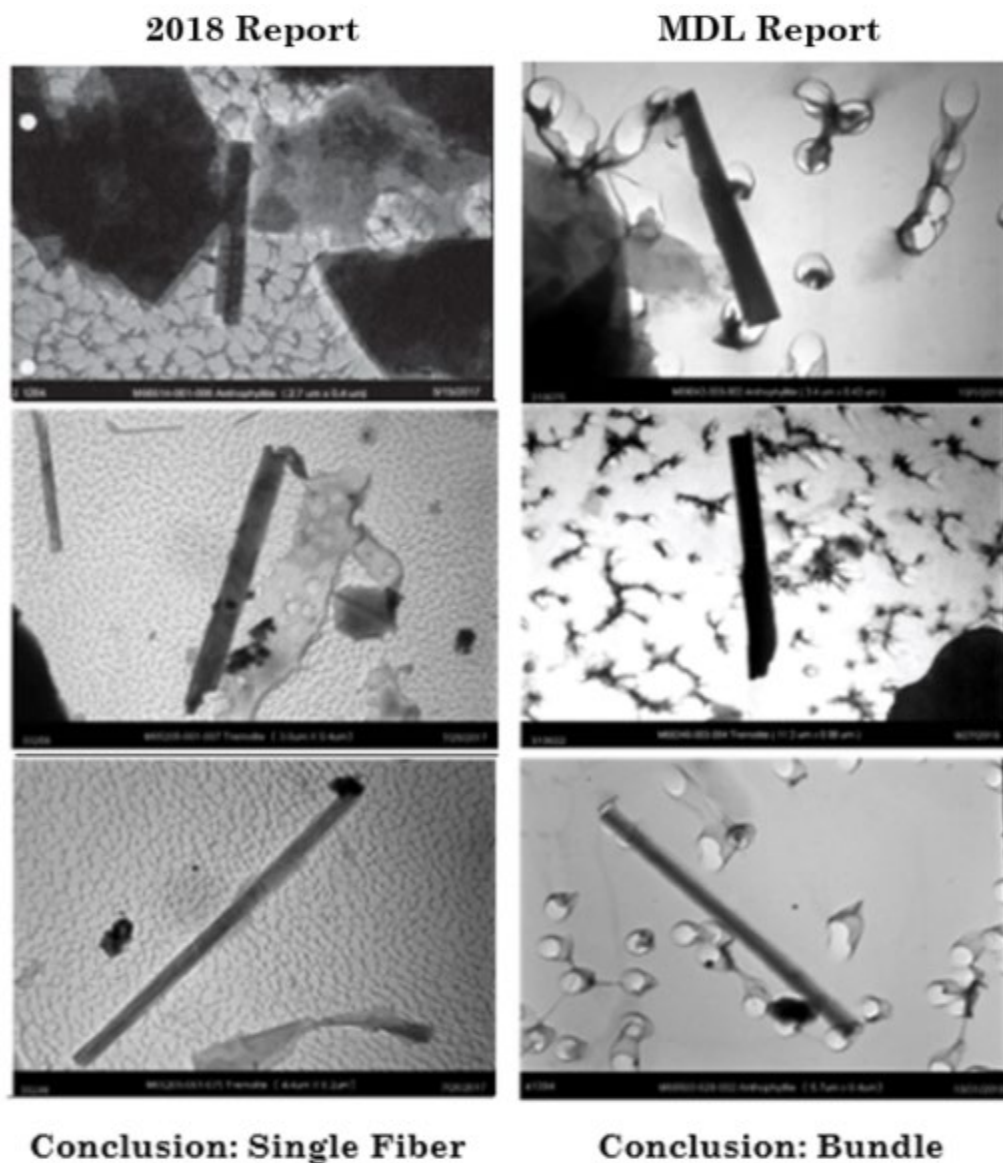
A “methodology” that consists of the subjective interpretation of pictures “completely detached from any objective criteria” poses a tremendous risk of results-oriented *ipse dixit*. *U.S. v. Williams*, No. 3:13-CR-00764-WHO-1, 2017 WL 3498694, at *10 (N.D. Cal. Aug. 15, 2017) (criticizing expert opinion as “untestable”). That is clear from Drs. Longo and Rigler’s results. The particles identified as bundles are slab-like, with no splayed ends, like the following:



²⁰² (See, e.g., Longo 2/5/19 MDL Dep. 250:14-16.)

²⁰³ (*Id.* 57:3-5; see also Longo Rimondi Tr. Vol. I 107:12-13, 107:18-19, 171:21-22 (same).)

More fundamentally, their classifications have changed over time. Compare Dr. Longo's classifications of structures in his March 2018 report with that of similar structures in his November 2018 report issued for this proceeding:²⁰⁴

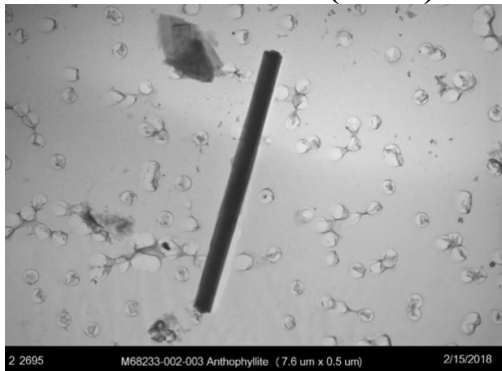


²⁰⁴ (On left: Suppl. Rpt. of William E. Longo, Ph.D. and Mark W. Rigler, Ph.D., at 31, 32, 34, 55, 106, 617, 634, Mar. 11, 2018 (“Longo 3/11/2018 Rep.”) (attached as Ex. 75 to Bush Decl.). On right: Longo Rep. at 240, 248, 585, 595, 1662, 1676 (11/14/18 MDL Report) (attached as Ex. 76 to Bush Decl.).)

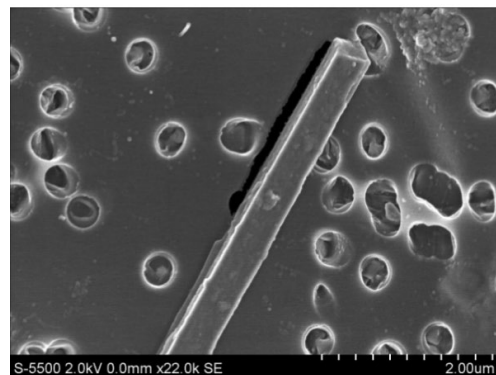
Despite the obvious similarities in these images, what Dr. Longo saw changed as litigation on this issue proceeded. This unexplained “sudden reversal of opinion” alone “seriously undermines the reliability of” Drs. Longo and Rigler’s methodology. *Fireman’s Fund Ins. Co. v. Canon U.S.A., Inc.*, 394 F.3d 1054, 1059 (8th Cir. 2005).

In fact, defense expert Dr. Sanchez uses scanning electron microscopy (“SEM”) on the very same particles that Dr. Longo and Dr. Rigler identify as bundles. Unlike TEM which provides a silhouette of the particle, SEM can provide much more detail regarding the surface characteristics of the particle. The SEM images make clear that what MAS is calling bundles are not bundles.²⁰⁵

MAS “Bundle” (TEM)



Same Particle On SEM



Second, the subjective nature of Drs. Longo and Rigler’s approach to bundles is illustrated by their own internal quality-control testing. Dr. Longo and

²⁰⁵ (Sanchez SEM Review at 21-23 (attached as Ex. 117 to Bush Decl.); *see also* MAS Rebuttal Rep. of Matthew S. Sanchez, Ph.D., Aug. 30, 2019, App’x C at 5. (attached as Ex. 118 to Bush Decl.).)

the analysts at his laboratory cannot consistently identify a “bundle” – a fact obvious from a study *that Dr. Longo himself commissioned* on the accuracy of his methodology.

Four microscopists from Dr. Longo’s lab were asked to analyze the same TEM grid openings.²⁰⁶ They looked at the same 25 TEM “grid openings” of an off-the-shelf Johnson’s Baby Powder container that had been spiked with asbestos to reach a concentration of 0.3 percent.²⁰⁷ Among other things, the microscopists were directed to determine whether what they saw was a fiber, a bundle, or a non-detect.²⁰⁸ The idea behind this exercise was to calculate his laboratory analysts’ error rate in identifying asbestos particles in a talcum powder sample.²⁰⁹

²⁰⁶ (See MAS TEM Coefficient of Variation for Tremolite and Anthophyllite in Talc: A Quality Control Study at 1, Sept. 6, 2018 (“MAS CoV Rep.”) (attached as Ex. 77 to Bush Decl.)) A TEM grid opening is what one sees when peering through a TEM, separating the visual field into “grids.” (Dep. of William E. Longo, Ph.D. 56:4-56:8, *Von Salzen v. Am. Int’l Indus. Inc.*, No. BC6805786 (Cal. Super. Ct. June 27, 2018) (attached as Ex. 78 to Bush Decl.) (“In a TEM grid, your field of view at 200x is most of the grid openings, or 50X. At 20,000 to 25,000 your view is approximately 1/20 of the grid opening, and a grid opening is 100 microns by 100 microns.”).)

²⁰⁷ (MAS CoV Rep. at 1.)

²⁰⁸ (*Id.* at 5-12.)

²⁰⁹ (See generally MAS CoV Rep.; Longo *Rimondi* Tr. Vol. I 169:9-171:15.)

The results were staggering: The four analysts agreed *only one time*, and then only for a fiber; in other words, they never agreed on a specimen as a “bundle”:²¹⁰

Grid Opening	(Analyst 1) Structure	(Analyst 2) Structure	(Analyst 3) Structure	(Analyst 4) Structure
A8-E2	Bundle	Fiber	Fiber	Bundle
A8-E4	Fiber	Fiber	Fiber	Fiber
A8-E5	Bundle	Bundle	Bundle	Fiber
A8-E7	Fiber	Bundle	Fiber	Fiber
A8-E8	Bundle	Fiber	Bundle	Fiber
A8-E9	Bundle	Bundle	Bundle	Fiber
A8-F2	Bundle	Bundle	Fiber	Bundle
A8-G1	Bundle	Bundle	Bundle	Fiber
A8-G4				Fiber
A8-G5		Bundle		
A8-G6	Bundle	Fiber	Bundle	Bundle

Note, this was a test to determine *consistency* – it was not a test for *accuracy*.

There is no way of confirming that even the single sample upon which all four analysts agreed was correctly identified. All that Dr. Rigler could say about this inconsistency was the nonsensical response that *all four* analysts were right *each time*.²¹¹ That is obviously not possible.

²¹⁰ (See MAS CoV Rep. at 5-12; see also Rigler 2/6/19 MDL Dep. 177:6-189:23; Longo Rimondi Tr. Vol. I 171:3-11.) The amount the analysts vary is called a “coefficient of variation” or “CoV.” Dr. Longo holds out this report as proving that his analysts have a CoV of just six percent. Yet this rate only applies to whether they identified an amphibole particle *at all*. (Longo Rimondi Tr. Vol. I 171:11-15.) This does not capture the tremendous disagreement between the analysts as to whether a particle was a fiber or a bundle.

²¹¹ (Rigler 2/6/19 MDL Dep. 184:20-24.)

The inability of MAS analysts to replicate Dr. Longo's results and consistently agree on whether a structure is a bundle is a serious problem. "Scientific methodology today is based on generating hypotheses and testing them," which "is what distinguishes science from other fields of human inquiry." *Daubert*, 509 U.S. at 593. In other words, "reproducible testing is a hallmark of reliable science." *Rembrandt Vision Techs., L.P. v. Johnson & Johnson Vision Care, Inc.*, 282 F.R.D. 655, 667 (M.D. Fla. 2012) (internal citations omitted). As discussed above, "a key question" under *Daubert* and Rule 702 is "whether [a methodology] has been tested and independently validated or replicated." *Ruffin*, 149 F.3d at 297 (4th Cir. 1998); *see also Paoli II*, 35 F.3d at 742 (describing requirement of "testability"); *see also U.S. v. Hebshie*, 754 F. Supp. 2d 89, 125 (D. Mass. 2010) (describing reproducibility as "the sine qua non of 'science'").

Here, Dr. Longo's "methodology" is worse than untested; it has been proven incapable of replication – and thus unreliable. The fact that even Dr. Longo's own employees "reached radically different findings and conclusions" when asked to distinguish between fibers and bundles shows that they were simply "unable to replicate [his] findings" in the way necessary to demonstrate reliability. *Ruffin*, 149 F.3d at 297-98 (affirming exclusion of expert testimony where attempts to replicate the study had failed). For this reason alone, Dr. Longo's purported identification of "bundles" must be excluded under Rule 702. *See, e.g., id.; Williams*, 2017 WL

3498694, at *10 (excluding expert testimony that “was so subjective that it could even vary between analysts at [the expert’s laboratory]”); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *13 (E.D. Pa. Feb. 1, 2001) (“Dr. Bloor could not reproduce his own results when asked to re-score the slides using his own method.”); *U.S. v. Johnson*, 122 F. Supp. 3d 272, 330 (M.D.N.C. 2015) (excluding expert testimony because expert’s subjective “methodology is seriously flawed and cannot be replicated”).

The reason “an expert’s testimony should be excluded if testing his methodology does not generate consistent results” is because “[i]nconsistency of results demonstrates the method is ‘unreliable because it is subjective and unreproducible.’” *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 559 (W.D. Pa. 2003) (citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 747 (3d Cir. 2000)). That could not be more true here. Dr. Longo’s “method” of distinguishing between fibers and bundles is a purely subjective and highly malleable inquiry. Its subjective character gives Dr. Longo license to make things up with impunity. This results-oriented *ipse dixit* cannot and does not pass muster under Rule 702 and *Daubert. Joiner*, 522 U.S. at 146 (“Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”); *see also, e.g., Durkin v. Equifax*

Check Servs., Inc., 406 F.3d 410, 421 (7th Cir. 2005) (affirming exclusion of “untestable say-so”).

III. This Court Should Exclude Plaintiffs’ Experts’ Opinions That The Levels And Types of Asbestos Alleged To Be Present In Defendants’ Talc Products Cause Ovarian Cancer.

Sixteen of plaintiffs’ experts seek to piggyback off of Drs. Longo and Rigler’s testing and opine that the alleged asbestos in cosmetic talc causes ovarian cancer.²¹² These opinions should be excluded.

²¹² (See, e.g., Rep. of Ellen Blair Smith, M.D. at 8-9, Nov. 16, 2018 (attached as Ex. 79 to Bush Decl.); Rep. of Arch Carson, M.D., Ph.D. at 5, Nov. 16, 2018 (“Carson Rep.”) (attached as Ex. 80 to Bush Decl.); Second Am. Rep. of Daniel L. Clarke-Pearson, MD, Nov. 15, 2023 (“Clarke-Pearson Rep.”) (attached as Ex. 81 to Bush Decl.); Rep. of Michele L. Cote, Ph.D., M.P.H., Nov. 15, 2023 (“Cote Rep.”) (attached as Ex. 82 to Bush Decl.); Rep. of Sarah E. Kane, M.D. at 32-33, Nov. 15, 2018 (“Kane Rep.”) (attached as Ex. 83 to Bush Decl.); Am. Rep. of Shawn Levy, Ph.D., Nov. 15, 2023 (attached as Ex. 84 to Bush Decl.); Rep. of Anne McTiernan, M.D., Ph.D., Nov. 15, 2023 (“McTiernan Rep.”) (attached as Ex. 85 to Bush Decl.); Rep. of Patricia Moorman, MSPH, Ph.D., Nov. 16, 2018 (“Moorman Rep.”) (attached as Ex. 86 to Bush Decl.); Second Am. Rep. of Laura Plunkett, Ph.D., DABT, Nov. 15, 2023 (“Plunkett Rep.”) (attached as Ex. 87 to Bush Decl.); Am. Rep. of William Sage, MD, JD, Nov. 15, 2023 (“Sage Rep.”) (attached as Ex. 88 to Bush Decl.); Second Am. Rep. of Jack Siemiatycki, MSc, Ph.D., Nov. 15, 2023 (“Siemiatycki Rep.”) (attached as Ex. 89 to Bush Decl.); Suppl. Rep. of Sonal Singh, MD, MPH, Nov. 15, 2023 (“Singh Rep.”) (attached as Ex. 90 to Bush Decl.); Second Am. Rep. of Rebecca Smith-Bindman, MD, Nov. 15, 2023 (“Smith-Bindman Rep.”) (attached as Ex. 91 to Bush Decl.); Second Am. Rep. of Judith Wolf, MD, Nov. 15, 2023 (“Wolf Rep.”) (attached as Ex. 92 to Bush Decl.).)

Additionally, Dr. Godleski in his case-specific report for *Newsome* refers to a particle of tremolite found in the plaintiff’s tissue that has an aspect ratio of 2:1—what even Plaintiffs’ experts such as Dr. Longo would agree is not asbestos. (Rep. of Dr. John Godleski Re: *Newsome*, June 24, 2021, at 3 (“Godleski *Newsome* Rep.”) (attached as Ex. 93 to Bush Decl.)). In his case-specific report for *Gallardo*,

A. Background on the science addressing the potential relationship between asbestos and ovarian cancer.

Although studies have extensively examined asbestos in relation to diseases such as mesothelioma, “[t]he relationship between asbestos exposure and ovarian cancer is not as well understood.”²¹³ As IARC observed in 2012, “[t]he published literature examining the association between asbestos exposure and cancer of the ovaries is relatively sparse.”²¹⁴ This is in part due to a “[s]mall number[] of cases” and the fact that far “fewer women than men have been exposed to asbestos, particularly in [the] more heavily exposed occupational settings” that have been the predominant focus of the literature.²¹⁵

Of the studies that have been done, results are mixed. The majority have *not* shown a statistically significant association between asbestos exposure and ovarian

he refers to plaintiff tissue findings with particles “within 5% of the accepted Mg/Si atomic weight percent ratio” for tremolite. (Rep. of Dr. John Godleski Re: Gallardo July 21, 2021, at 6 (“Godleski Gallardo Rep.”) (attached as Ex. 94 to Bush Decl.)). Even if these findings represented asbestos, his case-specific causation opinions regarding asbestos should be excluded for the same reasons discussed below: Dr. Godleski makes no attempt to compare these results to the epidemiology literature high occupational levels of exposure to a far more potent type of asbestos.

²¹³ Reid et al., *Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis*, 20(7) Cancer Epidemiol. Biomarkers & Prev. 1287, 1287 (2011) (“Reid 2011”) (attached as Ex. 95 to Bush Decl.).

²¹⁴ IARC 2012 Monograph at 253.

²¹⁵ Reid 2011 at 1287.

cancer.²¹⁶ This includes the only three studies that have examined environmental, rather than occupational, asbestos exposure: (1) a 2008 study of 2,552 women living in an asbestos mining town (SMR 1.26; 95% CI: 0.58-2.40);²¹⁷ (2) a 2009 analysis in the same population (SIR 1.18; 95% CI: 0.45-1.91);²¹⁸ and (3) a 2007 study of family members of men employed at an asbestos-cement factory in Italy (SMR 1.42;

²¹⁶ See *id.* at 1293 fig. 1 (chart showing the 16 studies, 12 of which did not report statistically significant results); *id.* at 1294 (“The present study has shown that 4 of 14 cohort studies reported a statistically significant excess rate for ovarian cancer among women exposed to asbestos. Of the remaining 10 studies, 5 reported a tendency to excess but failed to reach statistical significance and 5 reported rates that were similar to those of their reference populations. Strong evidence of consistency was not observed among these studies, although no study reported any protective effect.”).

²¹⁷ Reid et al., *Cancer Incidence Among Women and Girls Environmentally and Occupationally Exposed to Blue Asbestos at Wittenoom, Western Australia*, 122 Int’l J. Cancer 2337 (2008) (“Reid 2008”) (attached as Ex. 96 to Bush Decl.). “SMR” means “standardized mortality ratio” and reports the number of deaths attributable to disease in a study population relative to the number of such deaths expected in the broader population. (“SIR” – “standardized incidence ratio” – is a similar ratio that measures relative incidence of disease rather than mortality.) The “95% CI” reflects the 95% confidence interval. Confidence intervals are explained in greater detail in Defendants’ General Causation brief, but as relevant here, a confidence interval is intended to show the range of possible ratios that reflect the true relationship between the study population and the broader population. An interval that starts below and ends above 1.0 is deemed not statistically significant because 1.0 reflects equal risk between the two groups.

²¹⁸ Reid et al., *Gynecologic and Breast Cancers in Women After Exposure to Blue Asbestos at Wittenoom*, 18 Cancer Epidemiol. Biomarkers & Prev. 140 (2009) (“Reid 2009”) (attached as Ex. 97 to Bush Decl.) (analysis of ovarian cancer incidence in the same population (SIR 1.18; 95% CI: 0.45-1.91).).

95% CI: 0.71-2.54).²¹⁹ Some studies examining populations that sustained ***heavy occupational exposure to asbestos*** (i.e., female workers in factories that made asbestos products) have shown a statistically significant association between that exposure and ovarian cancer incidence or mortality.²²⁰

The results of these studies have been analyzed in several recent meta-analyses. One such review²²¹ calculated an overall SMR of 1.75 (95% CI: 1.45-2.10) across 16 studies, but cautioned that the association was potentially inflated due to other diseases, such as peritoneal mesothelioma, being misclassified as ovarian cancer on subjects' death certificates.²²² The authors of a different 2011 meta-

²¹⁹ Ferrante et al., *Cancer Mortality and Incidence of Mesothelioma in a Cohort of Wives of Asbestos Workers in Casale Monferrato, Italy*, 115 *Envtl. Health Perspectives* 1401 (2007) ("Ferrante 2007") (attached as Ex. 98 to Bush Decl.).

²²⁰ See, e.g., Reid 2011 at 1291 ("Statistically significant excess mortality or incidence of cancer of the ovary was reported in 4 of the 14 cohort studies").

²²¹ Reid 2011.

²²² (Expert Report of H. Nadia Moore, Ph.D., D.A.B.T., E.R.T. at 42, Feb. 25, 2019 (attached as Ex. 99 to Bush Decl.)) See Reid 2011 at 1287 (explaining that many studies ascertained mortality from death certificates, "[t]he accuracy of [which] has been questioned repeatedly"; observing that it has been "particularly difficult to distinguish between peritoneal mesothelioma and ovarian serous carcinoma"), *id.* at 1291, 1294; see also Camargo et al., *Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis*, 119 *Envtl. Health Perspectives* 1211, 1215-16 (2011) ("Camargo 2011") (attached as Ex. 100 to Bush Decl.) (observing that "until recently it has been very difficult to distinguish pathologically between peritoneal mesothelioma and ovarian cancer" and that earlier meta-analyses concluded that they could not conclude causality despite evidence of an association because of concerns about tumor misclassification and failure to account for known risk factors).

analysis “restricted to highly exposed women” reported “findings . . . consistent with the hypothesis that exposure to asbestos is associated with an increased risk of ovarian cancer.”²²³ In its 2012 Monograph, IARC concluded that the evidence supports an inference that asbestos exposure causes ovarian cancer, but expressly based this conclusion “on five strongly positive cohort mortality studies of women with *heavy occupational exposure* to asbestos.”²²⁴ The non-occupational studies, IARC observed, exhibited “positive, though *non-significant*, increases in [] ovarian cancer.”²²⁵ IARC’s conclusions on this issue have been called into question by the scientific community.²²⁶

Finally, the studies finding an association between asbestos and ovarian cancer generally involve exposure to crocidolite asbestos – regarded as the most potent of the various asbestos types, a fact that IARC and the recent meta-analyses concerning asbestos and ovarian cancer have all highlighted.²²⁷

²²³ Camargo 2011 at 1216.

²²⁴ IARC 2012 Monograph at 256 (emphasis added).

²²⁵ *Id.* (emphasis added).

²²⁶ As the authors of the Reid 2011 meta-analysis suggested, “the IARC decision to determine asbestos exposure as a cause of ovarian cancer was premature and not wholly supported by the evidence.” Reid 2011 at 1294.

²²⁷ *See id.* at 1291 (noting that crocidolite is “the most mesotheliogenic of the asbestos fibers”); Camargo 2011 at 1215 (noting that “[c]ohorts predominately exposed to crocidolite or mixed [i.e., crocidolite and chrysotile] asbestos showed larger SMRs than did those exposed only to chrysotile asbestos”); IARC 2012 Monograph at 242 (discussing studies finding no excess mortality for cancer of the

B. Plaintiffs' experts' asbestos-causation opinions should be excluded.

Even if asbestos were present in Defendants' products, Plaintiffs' experts' opinions' that the levels and types of asbestos at issue can cause ovarian cancer should be excluded. The relevant literature is hopelessly confounded by cases of *peritoneal mesothelioma* misdiagnosed as ovarian cancer. But even if asbestos could cause ovarian cancer, the literature is based on *heavy occupational* levels of exposure to the *most potent type of asbestos* (crocidolite). That says nothing about the ultra-trace levels of different, less potent types of asbestos that Dr. Longo and Dr. Rigler claim are present in Defendants' talc products—concentrations as low as 3.3 millionths of one percent.

1. The studies are confounded by peritoneal mesothelioma diagnoses.

As a threshold matter, the available epidemiological evidence does not even support a link between occupational levels of asbestos exposure and ovarian cancer. As a 2011 meta-analysis explained, the literature is weak and confounded by the reality that until very recently peritoneal mesothelioma was often misdiagnosed as ovarian cancer, raising a significant likelihood that the “ovarian

pharynx in amosite asbestos miners but an excess mortality rate for crocidolite miners and a higher risk rate for factory workers exposed to crocidolite than workers exposed to chrysotile); *id.* at 254-55 (relying on studies that involved crocidolite and, in some cases, also chrysotile).

cancer” cases associated with occupational asbestos exposure in prior studies were actually cases of mesothelioma—a different disease.²²⁸

2. The epidemiological literature does not support an association between asbestos and ovarian cancer at the levels described by Dr. Longo and Dr. Rigler.

Even if asbestos could cause ovarian cancer, perineal use of talc powder is not remotely comparable to the daily, high levels of occupational exposure to the most potent forms of asbestos experienced by the subjects of the studies Plaintiffs cite. Courts routinely reject causation opinions as unreliable where the alleged exposure was dissimilar from that of the subjects in the studies supposedly supporting the causal theory.²²⁹

²²⁸ Reid 2011 at 1287, 1292, 1294; *see also* Slomovitz et al., *Asbestos and ovarian cancer: examining the historical evidence*, Int’l J Gynecol. Cancer, 122, 126 (2021) (“Slomovitz 2021”) (attached as Ex. 101 to Bush Decl.) (discussing studies, questioning causal relationship between asbestos and ovarian cancer and noting that several studies have shown “a non-significant risk of ovarian cancer due to asbestos exposure . . .”).

²²⁹ *See, e.g., Cerna v. S. Fla. Bioavailability Clinic, Inc.*, 815 So. 2d 652, 656 (Fla. Dist. Ct. App.), *case dismissed*, 831 So. 2d 671 (Fla. 2002) (excluding expert opinion comparing articles on the effects of erythromycin in *in vitro* experiments involving high doses and altered pH conditions with studies on the effects of erythromycin on humans involving normal doses and normal conditions); *see also Boyer v. Weyerhaeuser Co.*, No. 14-cv-286-wmc et al., 2016 WL 705233, at *14, *22, *23 (W.D. Wis. Feb. 19, 2016) (striking expert opinions that non-occupational exposure to asbestos caused lung cancer because plaintiffs’ environmental exposure to defendant’s asbestos was not comparable to the occupational exposure involved in the study), *aff’d sub nom. Pecher v. Owens-Ill., Inc.*, 859 F.3d 396 (7th Cir. 2017); *Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 661-63 (D. Mass.

That is the situation here. As discussed above, of the 49 relevant containers Dr. Longo and Dr. Rigler tested from the J&J archive, the percentage of asbestos by weight they report ranges from .0092% at the high end (9.2 *thousandths* of a percent) to .0000033% (3.3 *millionths* of a percent) at the low end.²³⁰ Their median bottle was .000017%.²³¹ Because the studies on which plaintiffs rely involve “individuals whose circumstances were very different from those” here, they are “without evidentiary significance” and cannot support the opinions of plaintiffs’ experts. *Bostic v. Ga.-Pac. Corp.*, 439 S.W.3d 332, 358 (Tex. 2014) (citation omitted). And those occupational studies at issue involve individuals who *inhaled* asbestos, but the Court already “exclude[d] the inhalation theory presented by Plaintiffs’ general causation experts” on the grounds that it was not biologically plausible. *In re J&J*, 509 F. Supp. 3d at 177.

Moreover, studies involving non-occupational environmental exposure to asbestos *have not* found a statistically significant association between such

1997) (studies of occupational exposure to benzene could not be extrapolated to plaintiff exposed to significantly lower concentrations of benzene in bottled water); *Bostic v. Ga. Pac. Corp.*, 439 S.W.3d 332, 358 (Tex. 2014) (expert testimony was unreliable where studies of asbestos exposure did not deal with levels of exposure “comparable” to those experienced by plaintiff who was exposed only “outside of [his] primary employment”).

²³⁰ (Longo 4/17/19 *Weirick* Dep. 126:1-12); Longo 2/1/2019 MDL Rep. at 33, 41.)

²³¹ (Longo 4/17/19 *Weirick* Dep. 126:13-24; Longo 2/1/2019 MDL Rep. at 36.)

exposures and ovarian cancer.²³² For this reason, too, a causal connection cannot be supported. *See, e.g., In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 456 (E.D. Pa. 2014) (rejecting expert’s opinion where expert relied “on trends in non-statistically significant data to draw conclusions . . . rather than on replicated statistically significant findings”); *Smith v. Ford Motor Co.*, No. 2:08-cv-630, 2013 WL 214378, at *4 (D. Utah Jan. 18, 2013) (causation studies contradicted expert because “[a]ll of these studies have shown no statistically significant difference”).²³³

3. The epidemiological literature does not support an association between asbestos and ovarian cancer at the levels described by Dr. Longo and Dr. Rigler.

Plaintiffs’ experts’ causation opinions are also unreliable because the ovarian cancer studies they cite primarily involve exposure to large amounts of *crocidolite* asbestos, which is not alleged to be a contaminant of talc.

Courts have recognized in asbestos cases that “any epidemiological studies plaintiffs use to show the link between [a plaintiff’s] exposure to the defendants’

²³² *See* IARC 2012 Monograph at 254-55 (citing Reid 2009 (SIR 1.18 (95% CI 0.45-1.91)); Reid 2008 (SMR 1.26 (95% CI 0.58-2.40)); Ferrante 2007 (1.42 SMR (95% CI 0.71-2.54))).

²³³ Defendants anticipate that plaintiffs will challenge the importance of statistical significance, but for the reasons set forth in defendants’ general causation brief (*see* Mem. in Supp. of Mot. to Exclude Pls.’ Gen. Causation Ops. at 61-66), plaintiffs’ arguments lack scientific foundation. Moreover, there are no studies that have ever reported an ovarian cancer risk at the asbestos exposure levels alleged here, rendering the question of statistical significance moot in this context.

products and his mesothelioma must,” among other things, “involve the same type of asbestos fibers present in defendants’ products.” *See e.g., In re Asbestos Prods. Liab. Litig. (No. VI)*, No. MDL-875, E.D.Pa. No. 11-60070, 2012 WL 760739, at *8 (E.D. Pa. Feb. 17, 2012) (internal citations omitted), *report and recommendation adopted*, 2012 WL 775681 (E.D. Pa. Mar. 9, 2012). This is because it is “well-known that small differences in chemicals and molecular structure can and do result in substantial differences in toxicity and carcinogenicity.” *Lofgren v. Motorola*, No. CV 93-05521, 1998 WL 299925, at *23 (Super. Ct. Az., Maricopa Cnty.).

In asserting that asbestos can cause ovarian cancer, plaintiffs’ experts repeatedly cite IARC’s causation conclusion, which was based on five studies involving heavy occupational exposure predominantly to crocidolite asbestos.²³⁴ But those same studies and others make clear that crocidolite is uniquely toxic among the asbestos minerals.²³⁵ But crocidolite is not alleged to be present in Defendants’

²³⁴ (See, e.g., Carson Rep. at 5 (citing IARC as support for his statement that asbestos can cause ovarian cancer); Moorman Rep. at 35 (“IARC has stated that ‘a causal association between exposure to asbestos and cancer of the ovary was clearly established,’ based on strongly positive cohort mortality studies of women with occupational exposure to asbestos as well as studies of women with environmental exposure to asbestos.”).)

²³⁵ See Acheson et al., *Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up*, 39 Br J Ind Med 344, 347 (1982) (attached as Ex. 102 to Bush Decl.) (study reporting a “significant excess[] of mortality from lung and ovarian cancer” in workers exposed to crocidolite, but not workers exposed to chrysotile; “The probable

talc products,²³⁶ and there are no studies finding that exposure to the types of “asbestos” at issue here is associated with an increased risk of ovarian cancer.²³⁷

For this reason, too, plaintiffs’ experts’ opinions that asbestos in talc can cause ovarian cancer should be excluded. *See Lofgren*, 1998 WL 299925, at *23.

IV. This Court Should Exclude Dr. Cook and Dr. Krekeler’s Opinions Regarding Asbestos Contamination In The Source Mines.

The Court should exclude Drs. Cook and Krekeler’s opinions about the alleged presence of asbestos in talc because their opinions are not derived from reliable methods and are not supported by the data on which they rely.

explanation for the difference[] . . . lies in the different nature of the exposures in the two factories”); Reid 2011 at 1289-90 & tbl. 1, 1291 (setting forth these and other results indicating crocidolite is more toxic; separately observing that crocidolite is “the most mesotheliogenic of the asbestos fibers”); IARC 2012 Monograph at 242, 254-55 (concluding that there is a causal association based primarily on studies involving crocidolite); Camargo 2011 at 1215 (“Cohorts predominately exposed to crocidolite or mixed [i.e., crocidolite and chrysotile] asbestos showed larger SMRs than did those exposed only to chrysotile asbestos.”).

²³⁶ (See generally Longo 2/1/2019 MDL Rep. (failing to identify any crocidolite); see also Am. Rep. of Robert B. Cook, Ph.D., Jan. 22, 2019 (“Am. Cook Rep.”) (attached as Ex. 103 to Bush Decl.) (same); Report of Mark Krekeler, Ph.D., Nov. 16, 2018 (“Krekeler Rep.”) (attached as Ex. 104 to Bush Decl.) (same).)

²³⁷ See, e.g., Reid 2011 at 1289-90 & tbl. 1 (table showing that the studies reporting an association between asbestos and ovarian cancer have looked at exposure to crocidolite and chrysotile asbestos).

A. Drs. Cook And Krekeler unreliably base their opinions on counsel-generated collections and summaries of documents.

An expert may not be used as a mere vessel through which to funnel “information provided to her by a party.” *State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013) In particular, an expert cannot rely on a summary of the record evidence prepared by a party’s counsel. *See Crowley v. Chait*, 322 F. Supp. 2d 530, 546 (D.N.J. 2004).

But that is exactly what happened here. Pages 13-20 of Dr. Cook’s report contain a lengthy chart of company documents that is ***virtually identical*** to another chart of the same documents on pages 14-23 of Dr. Krekeler’s report. The charts contain not only the same documents, organized in the same fashion, but also (identical) substantive remarks about each document, either in the form of a quotation or a brief summary of its relevant contents.²³⁸ This is no cosmic coincidence, but rather reflects the same underlying work by plaintiffs’ counsel. As Dr. Krekeler explained at his deposition, he “asked [plaintiffs’] counsel to create the chart[.]”²³⁹ Thus, critically, the analyses of the documents reflected in these charts plainly were not the work of Drs. Cook and Krekeler but of counsel.

²³⁸ Drs. Cook and Krekeler also include identical tables of purported fibrous talc samples and appear to acknowledge that those tables were also made by counsel. (*See, e.g.*, Cook Dep. 56:8-19 (noting counsel helped with the tables).)

²³⁹ (Dep. of Mark Krekeler, Ph.D. (“Krekeler Dep.”) 39:9-13, Jan. 25, 2019 (attached as Ex. 105 to Bush Decl.)). Dr. Cook similarly acknowledged that the

B. The counsel-selected documents on which Drs. Cook and Krekeler rely in any event fail to furnish a reliable basis for their conclusions.

Drs. Cook and Krekeler's opinions are also unreliable and inadmissible because the documents on which they rely do not support their conclusions.

Expert testimony must be excluded when there is too great an analytical gap between the expert's opinion and the data on which the expert relies. *See Joiner*, 522 U.S. at 146; *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 159 (3d Cir. 1999) (expert's testimony was properly excluded because it "did not reliably flow from [the] data and methodology").

First, Drs. Cook and Krekeler rely on documents that have nothing to do with the issues presented in this litigation because they are from geographic regions and mines that were not sources of talc for Defendants' talc products.²⁴⁰ In addition, many of the data on which Drs. Cook and Krekeler rely were derived

tables were compiled by plaintiffs' counsel and sent to him to include in his report. (Cook Dep. 60:21-61:8.) When Dr. Cook was asked whether he had reviewed all of the documents in the tables, he responded, "I think I have." (*Id.* 60:6-8.)

²⁴⁰ *See, e.g.*, (Krekeler Rep. at 11 (Maanshaan deposit); Krekeler Dep. 195:22-25 (no evidence Maanshan deposit used in Defendants' products); Am. Cook Rep. at 10 (Val Chisone region but not Fontane mine); Cook Dep. 248:9-17 (acknowledging that the studies he cites do not identify chrysotile in the Fontane mine); Am. Cook Rep. at 11 (discussing the Carlton Mine, the Barton stateite quarry, the Holden talc quarry, Rochester verde antique quarry and the Mad River mine which were never sources of Defendants' talc); *id.* at 18 (Red Hill mine in California never used for Defendants' talc); Krekeler Rep. at 21 (same); *id.* at 15 (Frostbite mine never used for Defendants' talc products); Krekeler Rep. at 17 (same); Am. Cook Rep. at 23 (Gouverneur mine in New York never used for Defendants' talc products); Krekeler Rep. at 25 (Same).)

from testing in mines that were used to produce *industrial talc* – not cosmetic-grade talc. For instance, Drs. Cook and Krekeler rely on a test result for sample D-GI from the McCrone Laboratory, indicating that the sample contained chrysotile asbestos.²⁴¹ But that sample is from Gassetts Mill, which produced industrial talc that was never used in Defendants' talc products.²⁴²

Finally, Drs. Cook and Krekeler fail to differentiate between asbestiform and nonasbestiform minerals. Both Drs. Cook and Krekeler concede that amphiboles, such as tremolite, are not always asbestos; rather, they must form in the rare asbestiform habit to be asbestos.²⁴³ However, both Drs. Cook and Krekeler ignored this distinction in reaching their opinions. For example, Drs. Cook and Krekeler each cite reports from the Battelle Memorial Institute, an organization that tested cosmetic talc samples in the 1950s, for the proposition that cosmetic talc contained tremolite.²⁴⁴ But as Dr. Krekeler conceded at his deposition, the Battelle report does not indicate that the tremolite identified was of the asbestiform variety.²⁴⁵ The presence of nonasbestiform minerals in the mines where defendants sourced their

²⁴¹ (See, e.g., Am. Cook Rep. at 25; Krekeler Rep. at 26.)

²⁴² (See Rep. of Mary Poulton, Ph.D., Feb. 25, 2019, at 10 (attached as Ex. 106 to Bush Decl.) (citing JNJMX68_000002659).)

²⁴³ (See Krekeler Dep. 166:17-167:3 (acknowledging that tremolite may occur in an asbestiform or nonasbestiform habit); Cook Dep. 108:14-20 (agreeing that asbestos is defined as the asbestiform version of amphiboles).)

²⁴⁴ (See Am. Cook Rep. at 10; Krekeler Rep. at 9.)

²⁴⁵ (Krekeler Dep. 166:17-19.)

talc cannot support Drs. Cook and Krekeler's logical leap to the conclusion that those mines also contained the asbestiform variety of those minerals.

V. This Court Should Exclude Plaintiffs' Experts' Opinion That "Fibrous Talc" Causes Ovarian Cancer.

Perhaps sensing weaknesses in their asbestos allegations, several of plaintiffs' experts pivot to a backup theory that "fibrous talc" (*i.e.*, "elongated talc") allegedly present in Defendants' talc products renders them carcinogenic. All of these opinions suffer from the same central flaw: equating "asbestiform talc" with "elongated talc," despite the very authority they rely on stating those are two different things.²⁴⁶

An expert opinion should be excluded if "there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also, e.g., In re TMI Litig.*, 193 F.3d 613, 683

²⁴⁶ (McTiernan Rep. at 10, 76-77 (citing IARC 2010 and IARC 2012 Monographs); Wolf Rep. at 11-12, 20 (citing IARC 2012 Monograph); Plunkett Rep. ¶¶ 33, 101 (citing IARC 1987 Monograph, IARC 2010 Monograph, IARC 2012 Monograph); Rep. of Judith Zelikoff, Ph.D. at 4, Nov. 16, 2018 (citing IARC 2010 Monograph, IARC 2012 Monograph) (attached as Ex. 108 to Bush Decl.); Singh Rep. at 13-14 (citing IARC 2012 Monograph); Smith-Bindman Rep. at 4, 36 (citing IARC generally).)

Other experts mention the supposed carcinogenic potential of fibrous talc in a similarly perfunctory manner. These opinions should be excluded as well. (*See, e.g.,* Carson Rep. at 5; Clarke-Pearson Rep. at 7-8; Kane Rep. at 9-10; Am. Rep. of David A. Kessler, M.D. at 19-20, Nov. 15, 2023 (attached as Ex. 109 to Bush Decl.); Moorman Rep. at 35, 39; Siemiatycki Rep. at 27; Sage Rep. at 6-7, 27; Cote Rep. at 38; Godleski Gallardo Rep. at 6.)

(3d Cir. 1999) *amended*, 199 F.3d 158 (3d Cir. 2000) (excluding several experts for lack of fit and noting that expert opinion must be excluded when it does not “reliably flow from the facts known by the expert and the methodology used”) (citation omitted).

In keeping with this principle, an expert cannot depend on the carcinogenic effects of one substance to support a conclusion about a related substance without showing a basis for treating the two substances similarly. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 603-04 (D.N.J. 2002), *aff’d*, 68 F. App’x 356 (3d Cir. 2003) (excluding expert who relied on analogous chemicals because “[i]t is not contested that certain chemicals are structurally and functionally similar to one another . . . where the former is a known carcinogen and the latter is known to pose no carcinogenic risk whatsoever”); *see also, e.g., Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 472 (W.D. Pa. 2003) (“[G]iven the documented diversity of this chemical group, any reliance on general rules or principles purportedly associated with [these chemicals] as a group would be particularly inappropriate.”).

Plaintiffs’ testing experts Dr. Longo and Rigler purport to find “fibrous talc” particles in Defendants’ talc products. That just means talc particles that are long and thin—*i.e.*, elongated talc particles. Specifically, Dr. Longo and Dr. Rigler will call talc “fibrous” if it: (1) has an aspect ratio of 5:1 or greater, (2) is at least .5

micrometers in length, and (3) has substantially parallel sides—without regard to the particle’s growth habit²⁴⁷

Plaintiffs’ experts claim that IARC has classified these “fibrous talc” particles as carcinogenic (Group 1) because it is essentially the same as asbestos. But that is just a flagrant misreading of the IARC monographs. IARC does *not* say that “fibrous talc” is a carcinogen. Rather, the name of the “Group-1 agent” is “talc containing asbestos or other *asbestiform fibres*.”²⁴⁸ And IARC makes clear that “asbestiform” does not mean “elongated.”²⁴⁹

IARC specifically says that “asbestiform fibre” means “any mineral, including talc, when it *grows* in an *asbestiform habit*.”²⁵⁰ It similarly states that “asbestiform describes the *pattern of growth* of a mineral that is referred to as a ‘habit.’”²⁵¹ Most critically, IARC says that talc may “***be elongated without being asbestiform***”²⁵² and that the term “asbestiform talc has *erroneously* been used for talc products that contain elongated mineral fragments that are not asbestiform.”²⁵³

²⁴⁷ (Longo 2/1/2019 MDL Rep. at 12.)

²⁴⁸ IARC 2010 Monograph at 39 (emphasis added).

²⁴⁹ *Id.* at 277.

²⁵⁰ *Id.* at 39 (emphasis added)

²⁵¹ *Id.* at 277 (emphasis added).

²⁵² *Id.* (emphasis added).

²⁵³ IARC 2012 Monograph at 230 (emphasis added).

But to achieve their goal here, Plaintiffs’ experts conflate “elongated” and “asbestiform” talc in exactly the way IARC says not to, while relying on IARC for their conclusions regarding these talc particles’ supposed carcinogenicity. IARC simply does not say that elongated talc particles—all Plaintiffs’ testing experts claim to be finding in Defendants’ products—is a Group 1 agent.

While the statements above from IARC are clear enough on their own, IARC even describes *Defendants’ own talc sources as non-asbestiform talc*. Table 2.1 of the IARC 2010 monograph lists studies involving “non-asbestiform talc.”²⁵⁴ That table includes the Selevan study of Vermont talc where Defendants sourced their talc from for a period of time and the Rubino study of Italian talc where Defendants stored their talc for a period of time.²⁵⁵ And to be *absolutely clear* that “elongated” does not mean “asbestiform,” IARC even describes the Selevan study of non-asbestiform talc as reporting “elongated talc particles.”²⁵⁶

IARC states that talc must form in a particular asbestiform habit to fall into the category of a “Group-1 agent.” And it specifically says talc can be elongated without being asbestiform. But all Dr. Longo and Dr. Rigler claim to find is elongated talc, regardless of whether it formed in the asbestiform habit. Plaintiffs’

²⁵⁴ IARC 2010 Monograph at 319.

²⁵⁵ *Id.* at 319-320.

²⁵⁶ *Id.* at 296.

causation experts equate elongated talc with asbestiform talc to claim that IARC supports that elongated/fibrous talc is a Group-1 agent despite IARC expressly stating those two are not to be equated. This opinion should therefore be excluded as reflecting an unreliable application of the principles and methods to the facts of the case.

To the extent Plaintiffs plan to rely on the recent announcement regarding IARC's upcoming but as-yet unpublished update to its monograph on talc, that announcement only further illustrates that Plaintiffs' experts' methodology is flawed. At its essence, their theory boils down to the proposition that "fibrous talc," and "asbestos" are effectively the same, and this Court should simply assume that they could result in the same carcinogenic outcomes. But the Lancet article announcing the anticipated 2025 updated IARC monograph on talc in no way helps their novel cause. To the contrary, the announcement expressly states that even "asbestiform talc is not asbestos."²⁵⁷ In other words, the announcement only further illustrates that only asbestos is asbestos, and Plaintiffs' efforts to conjure up the effects of asbestos without the presence of asbestos is wholly lacking scientific support.

²⁵⁷ (Stayner et al., *Carcinogenicity of talc and acrylonitrile*, The Lancet (July 5, 2024) (attached as Ex. 110 to Bush Decl.).)

In short, neither the 2010 monograph nor the unreleased update serve as support for Plaintiffs' experts' false proposition that different fibers should all be treated the same. The so-called "fibrous talc" theory should therefore be excluded under Rule 702.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court exclude Plaintiffs' experts' opinions regarding the alleged presence of asbestos in defendants' talcum powder, exclude Plaintiffs' experts' opinions that asbestos causes ovarian cancer, and exclude Plaintiffs' experts' opinions that "fibrous talc" causes ovarian cancer.

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Respectfully submitted,

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CERTIFICATION OF SERVICE

I hereby certify that on July 23, 2024, a true and correct copy of the foregoing motion was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

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